IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William Vainchenker et al.
Title:	IDENTIFICATION OF A JAK2 MUTATION INVOLVED IN VAQUEZ POLYGLOBULIA
Appl. No.:	10/580,458
International Filing Date:	10/26/2005
371(c) Date:	5/24/2006
Examiner:	Sheridan Swope
Art Unit:	1652
Confirmation Number:	1466

INFORMATION DISCLOSURE STATEMENT UNDER MPEP § 2001.06(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with MPEP § 2001.06(c) Applicants herby bring to the attention of the Patent Office that related US 7,429,456 is the subject of the following litigations:

***BIO-REFERENCE LABORATIORIES, INC., Plaintiff v. IPSOGEN S.A. AND IPSOGEN, INC., Defendants*, United States District Court for the District of New Jersey, Civil Case No. 2:09-cv-06017-SRC-MAS**

***BIO-REFERENCE LABORATORIES, INC., Plaintiff v. ASSISTANCE PUBLIQUE – HOPITAUX DE PARIS, et al., Defendants*, United States District Court for the District of Columbia, Case No.: 1:10-cv-00292-HHK**

A copy of the Complaint as filed in redacted form with the New Jersey court is submitted herewith.

Applicants note that the District of Columbia Complaint was filed under seal. Accordingly, Applicants have submitted the District of Columbia complaint in redacted form with redactions corresponding to the New Jersey Complaint.

Although Applicants believe that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account No. 19-0741.

Respectfully submitted,

Date 8-MAR-2010

By _____

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4059
Facsimile: (202) 672-5399

Rouget F. Henschel
Attorney for Applicant
Registration No. 39,221

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BIO-REFERENCE LABORATORIES, INC.
481 Edward H. Ross Drive
Elmwood park, New Jersey 07407,

Plaintiff,

v.

IPSOGEN S.A.
Case 923, 163 Avenue de Luminy
13288 Marseille Cedex 9
France,

and

IPSOGEN, INC.
700 Canal Street, 5th Floor
Stamford, Connecticut 06902

Defendants.

Case No.:

Jury Trial Demanded

Electronically Filed Document

COMPLAINT FOR DECLARATORY JUDGMENT AND FOR FALSE AND MISLEADING ADVERTISING

Plaintiff Bio-Reference Laboratories, Inc. ("Bio-Reference") is an independent full-service clinical laboratory, with specialty capabilities in oncology and genomics. Through its cancer diagnostics business unit, GenPath, Bio-Reference offers specialized services in pathology, cytogenetics, molecular diagnostics and personalized medicine. Defendants Ipsogen S.A. and Ipsogen, Inc. (collectively "Ipsogen") threatened Bio-Reference with patent infringement of U.S. Patent No. 7,429,456 (the "'456 patent"), entitled "Identification of a JAK2 Mutation in Polycythemia Vera," a patent that appears to be owned by Ipsogen S.A. and licensed to Ipsogen, Inc. Bio-Reference tried to negotiate a resolution of the dispute with Ipsogen. Ipsogen's demands, however, have been excessive, particularly in light of serious questions

concerning the '456 patent's validity and whether the limited scope of the patent's claims cover Bio-Reference's activities, as will be discussed further. Further, Ipsogen demanded that Bio-Reference purchase Ipsogen's diagnostic kits for clinical diagnostic use, an impermissible use under the Federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §301, *et. seq.*, because the kits may be used for research use only ("RUO") under the applicable regulations. Ipsogen's demands that Bio-Reference purchase its kits also represent an improper tying arrangement because the kits far exceed the limited method claims of the '456 patent. When Bio-Reference refused to put itself in a position to violate the law, Ipsogen demanded a license that required payment of exorbitant licensing fees.

Bio-Reference files this Complaint in response to Ipsogen's repeated threats that Bio-Reference take a license, buy Ipsogen's kits, or stop testing. Bio-Reference seeks judicial declarations that, even if assumed valid, the claims of the '456 patent are limited to detecting and recording "the presence" of a certain gene mutation and do not cover detecting or recording "the absence" of the gene mutation (Count I), that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006 (Count II), that the '456 patent claims are invalid (Counts III-VII), that Ipsogen has misused the '456 patent (Count VIII), that Bio-Reference has not infringed the '456 patent (Count IX), that, if Bio-Reference has infringed the '456 patent, the reasonable royalty owed to Ipsogen should be limited, given the limited scope of its claims (Count X), and that Ipsogen cannot rely on its existing license agreements or sales of its kits as evidence of damages because those licenses and sales violate federal law (Count XI). Finally, Bio-Reference brings a claim against Ipsogen for false and misleading advertising under the Lanham Act, 15 U.S.C. § 1125(a), (Count XII). In support of this action, Bio-Reference further alleges in detail:

NATURE AND BASIS OF THE ACTION

1. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*, the United States patent laws, 35 U.S.C. §§ 1, *et seq.* and the Lanham Act, 15 U.S.C. § 1125(a). Plaintiff requests judicial declarations of the parties' rights and liabilities with respect to Ipsogen's '456 patent. A copy of the '456 patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Bio-Reference is a publicly-traded New Jersey corporation, having its principal place of business at 481 Edward H. Ross Drive, Elmwood Park, New Jersey 07407.

3. Defendant Ipsogen S.A. is a French corporation headquartered in Marseilles, France, and is the assignee of record of the '456 Patent.

4. Upon information and belief, Defendant Ipsogen, Inc., a wholly owned subsidiary of Ipsogen S.A., is a Connecticut corporation having its principal place of business at 700 Canal Street, 5th floor, Stamford, Connecticut 06902. Upon information and belief, Ipsogen, Inc. is a licensee of the '456 patent. Ipsogen, Inc. is registered to do business in New Jersey and maintains a registered agent, United Corporate Services, at 80 Main Street, 5th Floor, West Orange, New Jersey, 07052.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, Title 35 of the United States Code, and under the Lanham Act, 15 U.S.C. §1125(a).

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1332, and 1338, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. As shown below, a justiciable case or controversy exists between the parties that is ripe for this Court's adjudication.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) & (d). A substantial part of the events and omissions giving rise to this suit occurred in the venue, because the Ipsogen conduct giving rise to this litigation was directed to Bio-Reference in New Jersey. And, Ipsogen S.A. is an alien and may be sued in any district.

8. This Court has personal jurisdiction over the defendants. Upon information and belief, Ipsogen S.A. and Ipsogen, Inc. solicit and conduct business in the state of New Jersey through their presence on the World Wide Web and their offering products for sale in New Jersey. Moreover, this suit arises out of Ipsogen's S.A.'s and Ipsogen's Inc.'s conduct directed to Bio-Reference in New Jersey to license Ipsogen S.A.'s and Ipsogen, Inc.'s intellectual property and to buy their goods for delivery to New Jersey.

9. In addition, Ipsogen, Inc. is generally present in New Jersey for purposes of *in personam* jurisdiction by virtue of its registering to do business in the state and maintaining a New Jersey registered agent. Ipsogen S.A. is generally present in New Jersey for purposes of *in personam* jurisdiction because Ipsogen, Inc. is its agent and alter-ego. Facts demonstrating that Ipsogen, Inc. is the alter ego of Ipsogen S.A. include: Ipsogen, Inc. is a wholly-owned subsidiary of Ipsogen S.A.; Ipsogen, Inc. and Ipsogen S.A. have interlocking directorates because Ipsogen, Inc.'s directors and officers are also directors and officer of Ipsogen S.A.; and, upon information and belief, Ipsogen S.A. conducts its intellectual property licensing and products sales in the United States through Ipsogen, Inc. Defendant Ipsogen S.A. so dominates and controls the affairs of Defendant Ipsogen, Inc., that their corporate separateness should not be respected. The corporate veil of Ipsogen, Inc. should be pierced so that Ipsogen S.A. is treated as the alter ego of Ipsogen, Inc.

STATEMENT OF FACTS

A. A COGNIZABLE CASE OR CONTROVERSY EXISTS BETWEEN IPSOGEN AND BIO-REFERENCE CONCERNING BIO-REFERENCE'S JAK2 DIAGNOSTIC TESTING.

1. The JAK2 Mutation.

10. In the Spring of 2005, several independent teams of researchers separately published papers reporting the identification of the JAK2 V617F genetic mutation ("JAK2 mutation")[1] that was present in a majority of patients with certain types of myeloproliferative disorders ("MPD"). MPD is a group of conditions that cause blood cells - platelets, white blood cells, and red blood cells - to grow abnormally in the bone marrow. For one particular MPD, Polycythemia Vera ("PV"), a particularly high percentage of diagnosed patients carried the JAK2 mutation.

11. These discoveries potentially presented a new means for diagnosing MPD, especially PV, by genetically screening patients for the mutation.

12. Prior to these discoveries, the standard way to diagnosis the condition biologically was to culture patient bone marrow tissue. This procedure was labor-intensive and burdensome on patients.

13. After reading these independent reports, Bio-Reference, through its cancer diagnostics unit GenPath, developed and marketed a JAK2 diagnostic test in March 2006.

---

[1] "JAK2 V617F" identifies a genetic mutation using a conventional nomenclature known to biologists. In this case "JAK2" identifies a particular gene that codes for a tyrosine kinase protein. "V617F" identifies that a substitution of valine ("V") amino acid to phenylalanine ("F") amino acid occurred at position 617 of the JAK2 amino acid sequence for tyrosine kinase.

2. Ipsogen's Contacts With Bio-Reference.

14. On January 9, 2007, Ipsogen sent a letter directed to Bio-Reference's "Legal Department" with the reference line:

> Re: Use of JAK2 V617F mutation technology in Myeloproliferative Disorders
>
> Patent Estate: Patent Application US10/580,458 filed October 26, 2005.[2]

(Ex. B)

15. In the letter, Ipsogen represented that it was "the exclusive licensee of intellectual property rights that relate to JAK2 V617F mutation technology" that "cover a number of territories including USA." The letter continued, "Our research indicates that you are using or could be interested in using this technology rather than purchasing the Ipsogen Kit product and wish [SIC] to ascertain whether you may require a license under our intellectual property." The letter enclosed a technology brief and a table summarizing licensing terms.

16. Shortly after receiving Ipsogen's January 9, 2007 letter, Bio-Reference received a follow-up telephone call on Ipsogen's behalf. The individual placing the call to Bio-Reference could not answer Bio-Reference's basic questions about Ipsogen's intellectual property, such as proof that Ipsogen owned the intellectual property, and would not confirm whether she was employed by Ipsogen.

17. Two follow-up emails from Ipsogen, dated January 17, 2007 and January 19, 2007, provided a copy of proposed license terms, a copy of the US10/580,458 patent application and url links to press releases indicating Ipsogen had acquired an interest in a pending patent application directed to the JAK2 mutation. (Exs. C & D)

---

[2] The US10/580,458 patent application did not result in the '456 patent.

18. After receiving these emails, Bio-Reference considered the information but did not hear back from Ipsogen until the middle of 2008.

19. On May 15, 2008, Ipsogen Vice President Susan Hertzberg sent an email to Bio-Reference stating:

> I have made several attempts at contact with your company but have been unable to get a response.
>
> ****
>
> We have already granted a small number of non-exclusive licenses under our [JAK2] intellectual property rights and do not expect to continue much longer with this option. **This will be our last attempt to contact you for this purpose.**
> If we do not hear from you **before June 15, 2008** we will conclude a lack of interest on your part in licensing rights to perform testing. Should our US patent grant, we will expect that Bio Reference will respect our intellectual property rights and immediately stop all JAK2 in-house testing by means other than Ipsogen Kits.

(Ex. E.)(emphasis in original)

20. On April 30, 2009, Ipsogen again wrote to Bio-Reference enclosing the cover page of the '456 patent[3] stating that Bio-Reference "is using the JAK2 V617F mutation technology for clinical diagnosis." (Ex. F) The letter closed, "We look forward to providing your lab with an appropriate solution that will meet your current and future needs while respecting our intellectual property ... you will shortly be contacted by an Ipsogen Regional Territory Manager."

21. In that letter, Ipsogen suggested that Bio-Reference purchase Ipsogen's JAK2 diagnostic kits. Ipsogen's JAK2 kits are not authorized for any use other than RUO. Bio-Reference cannot legally use these kits for clinical diagnostic testing. 21 C.F.R. 809.10(c)(2)(i)

---

[3] The '456 patent issued on September 30, 2008.

Ipsogen knows Bio-Reference is engaged in clinical diagnostic testing. To resolve the dispute, Ipsogen effectively demanded that Bio-Reference violate federal law.[4]

22. No Ipsogen Regional Territory Manager ever contacted Bio-Reference, despite Ipsogen's representation in its April 30, 2009 letter that such contact would occur.

23. On August 3, 2009, outside counsel for Ipsogen wrote to Bio-Reference's CEO requesting that Bio-Reference "consider the claims [of the '456 patent] in view of the attached document found on the web site of your business unit GenPath." (Ex G.)

24. Shortly thereafter, Bio-Reference's CIO responded to this letter with an email stating, "We would like to work out some reasonable arrangement with Ipsogen for resolution rather than drag things on with further investigation [of Ipsogen's claims].... We are confidant the matter can be resolved." (Ex. H)

25. On August 19, 2009, Ipsogen's attorney responded, offering terms that required Bio-Reference to cease its own JAK2 testing and to conduct future in-house testing only by purchase and use of Ipsogen's JAK2 test kits:

> If [Bio-Reference] elects to conduct its own JAK2 tests, [Bio-Reference] must buy JAK2 test kits from Ipsogen and validate the assay as necessary.

(Ex. I)

26. Ipsogen offered its JAK2 kit to Bio-Reference at a price of ___ per kit. By comparison, the material costs for Bio-Reference's in-house assay total about ten dollars.[5]

---

[4] *See* Section C ¶¶ 36-46, *supra*, at 11-13.

[5] Pending disposition of a Motion For Leave to File Under Seal Plaintiff has redacted certain portions of this Complaint in order to protect what defendants may deem to be confidential information.

27. On August 25, 2009, outside counsel for Bio-Reference responded to the August 19, 2009 letter, stating that Bio-Reference would respond following an evaluation of Bio-Reference's activities, the '456 patent, and the license terms proposed by Ipsogen. (Ex. J)

28. The next day, Ipsogen's attorney wrote back stating: "Ipsogen does not authorize Bio-Reference to run [its in-house JAK2] assay covered by the claims of U.S. Patent No. 7,429,456. Instead, Ipsogen expects Bio-Reference to stop any such activity." (Ex. K.)

29. For the next several months the parties and their respective counsel communicated concerning their differences over JAK2 testing and the '456 patent. As part of those communications, Bio-Reference advised Ipsogen of its view that the claims of the '456 patent were invalid and were not infringed by Bio-Reference's JAK2 testing.

30. Ipsogen demanded access to Bio-Reference's sensitive business information reflecting JAK2 testing volumes. Bio-Reference responded that it first required a confidential non-disclosure agreement.

31. On October 30, 2009, Ipsogen sent Bio-Reference an e-mail that attached a confidentiality agreement, demanding:

> If we do not have the signed [confidentiality] agreement and JAK2 data by the end of day today, we will consider that a sign of your unwillingness to cooperate with us on this matter and will expect that you will immediately start sending your JAK2 testing to an authorized provider If you do not send your JAK2 testing out at that point, we will proceed with next steps to protect our intellectual property.

(Ex. L.)(emphasis added)

32. On November 6, 2009, Bio-Reference confidentially provided the JAK2 test volume data to Ipsogen, but reminded Ipsogen of Bio-Reference's position that any act alleged to have been an infringement of the '456 patent could not include detecting the "absence" of the mutation (*i.e.*, a negative result). Bio-Reference reminded Ipsogen that, during prosecution,

Ipsogen had expressly cancelled the term "the absence" that appeared in the claims during prosecution to overcome rejections by the USPTO.

33. On November 10, 2009, Ipsogen sent an email to Bio-Reference, attaching a proposed sublicense:

> Attached please find the Ipsogen _____ Sublicense Agreement for JAK2.
>
> _____
>
> **You will have until November 30, 2009 [SIC] to execute this agreement. If it is not executed prior to this date, we expect you to send your JAK2 testing to an authorized provider.**

(Ex. M)(emphasis added)

34. Ipsogen's proposed _____ sublicense requires Bio-Reference to pay _____.

The Look-Back fee represents a trebling of the $35 running royalty fee. The trebling demonstrates Ipsogen's arrogance in dealing with Bio-Reference, dictating overreaching terms for a patent with limited scope and of questionable validity. In exchange for the license, Bio-Reference _____

35. This proposed sublicense requires Bio-Reference to _____ to Ipsogen for all JAK2 tests irrespective of whether the test detected and recorded the presence or the absence of the mutation. As explained more fully in section B.1, ¶¶ 39 to 43, the '456 patent claims are limited to detecting and recording only the presence of a JAK2 mutation; the claims do not cover the absence of the mutation.

36. In response to Ipsogen's November 11, 2009 ultimatum, Bio-Reference initiates this case.

B. THE '456 PATENT

37. On September 30, 2008, the United States Patent and Trademark Office ("USPTO") issued the '456 patent, listing "Ipsogen (Marseilles, FR)" as the assignee. The '456 patent issued with seven claims.

38. The '456 patent relates to the JAK2 mutation, which it refers to as the "V617F variant" of JAK2 (*see, e.g.*, Exhibit A, Abstract) or alternatively, the "JAK2 G1849T variant"[6] (*see, e.g.*, Exhibit A, col. 4, lines 35-40). According to the '456 patent, the detection of the "V617F variant" of JAK2 in a sample from a human patient is associated with certain MPD, such as PV. *See, e.g.*, Ex. A, Abstract.

1. The '456 Patent Claims Are Limited to Claiming the Detection and Recordation Only of the Presence, But Not the Absence, of the JAK2 Mutation.

39. Notably absent from the claims of the '456 patent are steps for detecting and recording the "absence" of the T in the JAK2 mutation. Ipsogen deliberately deleted the term "absence" from the claims to obtain USPTO approval for the '456 patent, as shown below.

40. Independent claims 1 and 2 as they appear in the '456 patent read (emphasis added):

> 1. An in vitro method to determine **the presence** of the G1849T mutation in the JAK2 gene in a human patient comprising:
>
> a) obtaining and analyzing a nucleic acid sample from the human patient;

---

[6] Whereas "JAK2 V617F" identifies a mutation based on the sequence of amino acids for which it coded (see footnote 1 above), "JAK2 G1849T" identifies the same mutation based on a corresponding DNA sequence. "JAK2" identifies a particular gene that codes for a tyrosine kinase enzyme. "G1849T" identifies that position 1849 of the JAK2 DNA coding sequence, guanine ("G") was substituted for thymine ("T").

b) detecting a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample; and

c) **recording the presence** of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample.

2. An *in vitro* method to determine if a human patient is currently suffering from or is likely to develop a myeloproliferative disorder selected from the group consisting of Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis comprising:

a) obtaining and analyzing a nucleic acid sample from the human patient;

b) detecting a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample; and

c) **recording the presence** of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample;
wherein the presence of a T at position 2343 of SEQ ID NO 2 indicates the human patient is currently suffering from or is likely to develop a myeloproliferative disorder selected from the group consisting of Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis.

41. However, as originally filed, in Application Number 11/934,359, independent claims 1, 17, and 20, were as follows:

1. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop a myeloproliferative disorder, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder.

17. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop the myeloproliferative disorder myelofibrosis, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder.

20. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop a myeloproliferative disorder, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder, wherein the nucleic acid sample is mRNA, and comprising amplifying by reverse transcriptase-polymerase chain reaction.

(Ex. N)

42. The USPTO issued a Final Office Action on May 29, 2008, rejecting Ipsogen's proposed claim language. (Ex. O) To overcome the rejections, Ipsogen amended its claims as follows (arrows showing Ipsogen's deleted language have been added for emphasis):

1. (Currently Amended) An *in vitro* method to determine the presence ~~or absence~~ of the V617F mutation in the JAK 2 gene, wherein the mutated JAK 2 gene is SEQ ID NO: 2, from a human patient, comprising:

analyzing a nucleic acid sample from the human patient, detecting the presence ~~or~~ ~~absence~~ of the V617F mutation in the JAK 2 gene in the nucleic acid sample from the human patient and recording the presence ~~or absence~~ of the mutation in the sample from the human patient, wherein the presence of the mutation in the JAK 2 gene in the sample indicates a myeloproliferative disorder in said human patient selected from Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis.

(Ex. P)

43. On August 12, 2008, the USPTO mailed Ipsogen a Notice of Allowance and Examiner's Amendment, canceling and rewriting two independent claims as they would later issue as claims 1 and 2 in the '456 patent. (Ex. Q)

C. THE IPSOGEN JAK2 TEST KITS CANNOT BE SOLD FOR CLINICAL DIAGNOSTIC TESTING

44. Ipsogen markets a line of JAK2 test kits under variants of the brand names MutaSearch™, MutaQuant™ and MutaScreen™. These kits qualify as medical devices and are regulated by the FDA under the FDCA. 21 U.S.C. § 321(h).

45. The FDCA sets forth labeling requirements for medical devices and prohibits the selling of misbranded medical devices in interstate commerce. 21 U.S.C. § 331(a). A device is misbranded if its labeling or advertising is false or misleading in any manner. 21 U.S.C. §§ 352(a), 352(q)(1).

46. Certain formal requirements apply to device labeling, and a failure to comply with any of those requirements renders the device misbranded. 21 U.S.C. §§ 352(b), 352(c), 352(e)(2); *see also* 21 C.F.R. §§ 801.1-801.6, 801.15.

47. Medical devices are considered misbranded if they are marketed in interstate commerce before complying with the FDA 510(k) pre-notification requirements or obtaining pre-market approval from the FDA. *See* 21 U.S.C. § 331(r); 21 U.S.C. § 331 (o).

48. Ipsogen is only authorized to market its JAK2 test kits for RUO. 21 U.S.C. § 352. RUO devices must be labeled and advertised as such. 21 C.F.R. § 809(c)(2)(i). Labeling or advertising an RUO for other uses, such as clinical diagnostic uses, is prohibited. 21 U.S.C. §331(k).

49. Upon information and belief, Ipsogen sells JAK2 V617F molecular products for screening and monitoring of MPD for clinical diagnostic purposes, even though such products are approved only for RUO. Upon information and belief, Ipsogen has not complied with the pre-notification requirements, nor has Ipsogen received any pre-market approval for its JAK2 kits for commercial use.

50. On April 30, 2009, Ipsogen's Vice President of Sales, North America, Thomas D. Bartel, sent Bio-Reference a letter stating, "Our research indicates that your organization is using the JAK2 V617F mutation technology for clinical diagnostic use (non research activities)" and

continues, "Ipsogen currently offers a comprehensive range of JAK2 V617F molecular products for the screening and monitoring of myeloproliferative disorders," including:

- JAK2 MutaScreen (ref.MSPP-01, MSPP-02), a simple and accurate PCR kit to assess the presence of the mutation in MPD's suspected subjects
- JAK2 MutaScreen + reference scale (ref. MSPP-03), a semi-quantitative real time PCR kit to estimate the mutation load in MPD's diagnosed patients
- JAK2 V617F MutaQuant (ref.MQPP-01), a sensitive and quantitative real-time PCR kit for the monitoring of the mutation load in MPD's diagnosed patient.

(Ex. F)

51. Bio-Reference declined to purchase the Ipsogen diagnostic kits because of, in large part, the RUO restriction. On June 18, 2009, Mr. Bartel again offered Bio-Reference the same RUO-approved JAK2 kits, despite knowing that Bio-Reference engages in commercial activities. (Ex. R)

52. On August 19, 2009, Ipsogen's counsel demanded Bio-Reference stop conducting its own clinical testing for JAK2 unless ", Bio-Reference [buys] JAK2 test kits from Ipsogen..." (Ex. I) Ipsogen knew that Bio-Reference engages in commercial activities and that Ipsogen's kit has the RUO limitation.

53. Upon information and belief, Ipsogen's conduct is not isolated to Bio-Reference. Upon information and belief, Ipsogen has required other clinical diagnostic labs that conduct JAK2 testing to purchase Ipsogen JAK2 test kits.

COUNT I

(Declaration that the Claims of the '456 Patent do not Encompass Detecting the Absence of the JAK2 Mutation)

54. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 53, as if set forth in full.

55. The meaning of the claims of the '456 patent constitutes an actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, between Bio-Reference and Ipsogen. If the '456 patent is found valid and infringed, then the meaning of the claim terms of the '456 patent will be important to calculating past and future damages for infringement.

56. Ipsogen has asserted to Bio-Reference that the claims of Ipsogen's '456 patent cover Bio-Reference's test results regardless of whether the particular test detects the presence or the absence of the JAK2 mutation, *i.e.*, the presence or absence of a "T in the JAK2 gene at the 2343 position."

57. In turn, Bio-Reference has repeatedly disputed Ipsogen's overbroad construction of the claims of the '456 patent, contending that the '456 patent claims, if valid, are limited to detecting and recording only **the presence** of a "T in the JAK2 gene at position 2343."

58. At the time the '456 patent issued, and to this date, a person of ordinary skill in the art, would have understood and would understand that the claims of the '456 patent encompass detecting and recording the presence, but not the absence, of a "T in the JAK2 gene at the 2343 position."

59. In any event, Ipsogen is estopped from asserting that the '456 patent claims include detecting and recording *the absence* of the T in the JAK2 gene at position 2343 because, during prosecution, to overcome a rejection of its original claims, Ipsogen amended those claims by deleting the term "or absence" from its proposed phrase "detecting the presence or absence." Accordingly, Ipsogen deliberately relinquished the noted subject matter during prosecution. Complaint ¶¶ 37-43, *supra.*

60. Bio-Reference is entitled to a declaratory judgment that the claims of the '456 patent encompass only detecting and recording the presence of the T in the JAK2 gene at

position 2343, but do not include detecting and recording the absence of the T in the JAK2 gene at position 2343.

COUNT II

(Declaration That the Claims of the '456 Patent are Entitled to a Priority Date No Earlier Than May 24, 2006)

61. Bio-Reference incorporates the allegations contained in paragraphs 1-60, as if set forth in full.

62. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the priority date to which the claims of the '456 patent are entitled. The claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006.

63. The '456 patent was filed as U.S. Appl. No. 11/934,359 on November 2, 2007 ("the '359 application"), as a divisional of U.S. Appl. No. 10/580,458, filed May 24, 2006 ("the '458 application"), which was the national stage entry of PCT Appl. No. PCT/EP05/55586, filed October 26, 2005 ("the '586 PCT application"), which claims foreign priority to French Appl. No. 0411480, filed October 27, 2004 ("the '480 FR application").

64. Ipsogen submitted the '359 application to the USPTO under "accelerated examination." Two requirements for accelerated examination are the Applicants' submission of a preexamination search statement and an accelerated examination support ("AES") document. The Manual of Patent Examining Procedure (the "MPEP")[7] requires that the AES document include an Information Disclosure Statement ("IDS") citing each reference deemed most closely related to the subject matter of each claim. MPEP 708.02(I)(1). The AES document must

[7] Published by the USPTO, the MPEP instructs patent examiners on the practices of procedures as for examination of a patent application.

include a showing of where each limitation of the claims finds support in the present specification, as well as in applications where priority benefit is being claimed, under 35 U.S.C. § 112, first paragraph, as required by MPEP 708.02(I)(5).[8]

65. Under the Patent Act and the MPEP rules, claims 1-7 of the '456 patent are not entitled to a filing date earlier than that of the '458 application, which was filed May 24, 2006, because neither the '586 PCT application nor the '480 FR application disclose every limitation of claim 1 in the manner required by 35 U.S.C. § 112, first paragraph.

66. First, neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for the claim term "*recording the presence of a T in the JAK2 gene*," recited in claims 1 and 2 of the '456 patent. The updated AES document submitted on April 21, 2008, was required specifically to show support for every limitation in the claims (original and amended) (Ex. S), but Ipsogen provided no support in the '586 PCT application or the '480 FR application for "recording the presence or absence of the mutation ...". Under 35 U.S.C. §§ 119, 120 and 365, claims 1-7 of the '456 patent are not entitled to the priority date of either application.

67. The lack of support in the updated AES document is notable because in his March 21, 2008 communication, the Examiner expressly stated that this limitation was not addressed in the original AES document. Furthermore, on page 7 of the Final Office Action dated May 29, 2008, the Examiner stated that "review of the [Applicants] cited parts of the parent specification and text searching *failed to reveal the support for recording*." (emphasis added).

---

[8] For any amendment to the claims that is not encompassed by the initial AES document, applicant is required to provide an updated AES document that encompasses the amended or new claims at the time of filing the amendment. *See* MPEP 708.02(a)(IV).

68. Second, neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for the claim term "*detecting*, a T in the JAK2 gene *at position 2343 of SEQ ID NO 2 in the sample*," used in the '456 patent claims. (emphasis added). The preamble of claim 1 of the '456 patent refers to nucleotide position "1849" in the JAK2 gene, while steps (b) and (c) refer to nucleotide position "2343" of SEQ ID NO: 2. Thus, issued claim 1 refers to *two* different nucleotide numbers to designate the mutation in the JAK2 gene.

69. Step (b) of issued claim 1 recites: "detecting a T in the JAK2 gene *at position 2343 of SEQ ID NO 2 in the sample*." (emphasis added). Neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for this step because the applications refers only to the JAK2 variant as either "V617F," or alternatively, the "g/t mutation at position 1849 hereinafter called G 1849T starting from the ATG marking the start of translation."

70. The only possible support for a T at position 2343 of SEQ ID NO: 2 is the sequence listing. However, the sequence listing itself does not provide guidance as to the relationship between G1849T and a T at position 2343 of SEQ ID NO: 2. For example, SEQ ID NO: 2 in both applications are described (incorrectly) as "G1849T mutation in JAK2 gene."

71. Moreover, SEQ ID NO: 2 represents the genomic DNA (and includes the non-coding region), thus, the sequence position corresponding to "1849" (when referring to the JAK2 coding region) is actually "2343" in SEQ ID NO: 2. As there are numerous ATG sites in SEQ ID NO: 2, it is unclear where translation begins and can only be ascertained by cross-referencing the amino acid sequence of SEQ ID NO: 1.

72. Bio-Reference is entitled to a declaratory judgment that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006.

COUNT III

(Declaration of Invalidity of Claims 1-3 of the '456 Patent Under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 102(a))

73. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 72, as if set forth in full.

74. An actual controversy exists between Bio-Reference and Ipsogen, within the meaning of 28 U.S.C. §§ 2201 and 2202, concerning the validity of the claims of the '456 patent.

75. Claims 1-3 of the '456 patent are invalid under 35 U.S.C. §§ 102(a) and/or 102(b).

76. 35 U.S.C. § 102(a) provides (or provides in pertinent part):

> A person shall be entitled to a patent ... unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

77. 35 U.S.C. § 102(b) provides (or provides in pertinent part):

> A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...

78. Because the earliest possible filing date to which the claims of the '456 patent can claim benefit is that of the parent application, Appl. No. 10/580,458, filed on May 24, 2006, any reference published before May 24, 2006, is eligible as intervening prior art under 35 U.S.C. § 102.[9]

---

[9] Count II establishes that the correct priority date for the '456 patent is May 24, 2006, and not either October 26, 2005 (the filing date of the '586 PCT application) or October 27, 2004 (the filing date of the French '480 application),

79. The following printed publications qualify as invalidating prior art as to claims 1-3 of the '456 patent under 35 U.S.C. §§ 102(a) & (b): Baxter, E.J. *et al.*, *Lancet* 365:1054-1061 (March 19, 2005)("Baxter")(Exhibit T); Levine, R.L. *et al.*, *Cancer Cell* 7:387-397 (published online March 24, 2005))("Levine")(Exhibit U); Kralovics, R. *et al.*, *N Engl. J. Med.* 352:1779-1790 (April 28, 2005) ("Kralovics") (Exhibit V); and Zhao, R. *et al.*, *J. Biol. Chem.* 280:22788-22792 (published online April 29, 2005)("Zhao") (Ex. W).

80. Baxter, Levine, Kralovics or Zhao disclose each and every limitation of claims 1-3 of the '456 patent, arranged the same way as in the claims.

81. Baxter, Levine, Kralovics, and Zhao were published between March 19, 2005, and April 29, 2005, more than one year before the May 24, 2006 filing date of the '458 application. Therefore, Baxter, Levine, Kralovics, and Zhao qualify as intervening prior art under 35 U.S.C. § 102(b).

82. Alternatively, even if Ipsogen somehow establishes that the '456 patent should be entitled to the filing date of the '586 PCT application, October 25, 2005, then Baxter, Levine, Kralovics, and Zhao still qualify as intervening prior art under 35 U.S.C. § 102(a).

83. Therefore, claims 1-3 are invalid under 35 U.S.C. §§ 102(b), or at least 102(a), as being anticipated by each of Baxter, Levine, Kralovics, or Zhao.

84. Bio-Reference is entitled to a declaratory judgment that claims 1-3 of the '456 patent are invalid pursuant to 35 U.S.C. §§ 102(a) and/or 102(b).

COUNT IV

(Declaration of Invalidity of Claims 1-7 of the '456 patent Under 35 U.S.C. § 112, First Paragraph, for Lack of Written Description)

85. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 84, as if set forth in full.

86. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the validity of the claims of the '456 patent. Bio-Reference seeks a declaratory judgment from this Court that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

87. 35 U.S.C. § 112, first paragraph, provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

88. The specification of the '456 patent and applications through which it claims priority do not describe the detecting and recording steps that appear in claims 1 and 2 of the '456 patent. Claims 3-7 of the '456 patent depend either directly or indirectly from claim 1. Therefore, claims 3-7 contain each and every limitation of claim 1. The "detecting" and "recording" steps are such limitations. Thus, Ipsogen has failed to provide a description of dependent claims 3-7 as well.

89. Ipsogen cannot rely upon the originally filed claims as evidence that the inventors possessed the invention of claims 1-7 of the '456 patent. The recording step did not appear originally in the '359 application, but was added to the claims by amendment on February 22, 2008, four months after the November 2, 2007 filing date for the '359 application. The specification that ultimately appears in the '456 patent first appeared in the '359 application and contains no description about the recording steps. (Ex. X)

90. The detecting step was added to the claims at a later date during prosecution of the '456 patent, by the August 12, 2008 Examiner's Amendment. Prior to the Examiner's

Amendment, independent claim 1 referred to "detecting the presence of the V617F mutation in the JAK2 gene" in the nucleic acid sample from the human patient. (Ex. P)

91. Even as of the most recent filing date of November 2, 2007, for the '359 application, one of ordinary skill in the art would not have understood Ipsogen to be in possession of the full scope of the claimed invention.

92. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

COUNT V

(Declaration of Invalidity of Claims 1 and 3-7 of the '456 Patent Under 35 U.S.C. § 112, First Paragraph, for Lack of Enablement)

93. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 92, as if set forth in full.

94. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the validity of the claims of the '456 patent. Claims 1 and 3-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement.

95. Claim 1 is directed to any *in vitro* method for determining the presence of the G1849T mutation in the JAK2 gene in a human patient comprising three steps. The scope of claim 1 is extremely broad and certainly much broader than the supporting disclosure. The claimed *in vitro* method is not limited in any way, *e.g.*, screening for a specific disease in a human patient, and encompasses any and all *in vitro* methods for determining the presence of the G1849T mutation in a human patient.

96. In addition, the *in vitro* method of claim 1 does not satisfy the utility requirement of 35 U.S.C. § 112, first paragraph. The *in vitro* method of claim 1 encompasses any and all *in*

vitro methods for screening for the presence of the G1849T mutation in a human patient. Therefore, claim 1 encompasses, more than just the diagnostic uses referred to in the '456 patent to diagnose three specific myeloproliferative diseases, extending to *any* other unspecified uses.

97. Further, both claim 1 and claim 2 recite the step of "recording the presence of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample," which appears as step (c) in both claims. This recording step is directed to any means for recording the presence of the recited JAK2 mutant in the claimed method, and thus is extremely broad.

98. Despite the breadth of the recording step of claims 1 and 2, the '456 patent, including its predecessor applications, do not provide any means for recording the presence of the JAK2 mutant. The "recording" step first appeared in a February 22, 2008 Amendment. (Ex. X) No support for that term appears either in the specification of the '359 application, in the Amendments submitted during accelerated examination, or in the updated AES document.

99. The '456 patent does not provide adequate direction or working examples to enable the full scope of claims 1 or 2. For instance, Examples 1 and 2 of the '456 patent, the latter of which was not added until the '586 PCT application, are directed to identifying the JAK2 mutation in PV patients and as a first intention diagnosis of erythrocytosis, respectively. Neither of these generally stated examples provides sufficient guidance to enable one of ordinary skill actually to perform the methods as claimed.

100. In view of the breadth of claim 1 and the failure of the '456 patent to provide a specific utility or sufficient guidance to practice the claimed method, undue experimentation will be required to perform the full scope of the invention of claim 1.

101. In view of the breadth of the recording step of claims 1 and 2, undue experimentation will be required to perform the full scope of the invention of claims 1 and 2.

102. Accordingly, claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph.

103. Claims 3-7, which depend from claim 1, also are invalid under 35 U.S.C. § 112, first paragraph. These dependent claims merely limit the means for carrying out the analyzing step of claim 1. However, claims 3-7 do nothing to limit the scope of the *in vitro* method of claim 1 or the recording step of claim 1 and, therefore, would encompass any and all *in vitro* methods for determining or recording the presence of the JAK2 mutation in a human patient. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement.

COUNT VI

(Declaratory Judgment of Invalidity of Claims 1-7 of the '456 Patent Under 35 U.S.C. § 112, Second Paragraph, as Indefinite)

104. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 103, as if set forth in full.

105. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the validity of the claims of the '456 patent. Claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as indefinite because claims 1-7 of the '456 patent fail to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention," as required by 35 U.S.C. § 112, second paragraph.

106. 35 U.S.C. § 112, second paragraph, provides:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

107. The '456 patent does not provide any description or guidance as to the scope of the term "recording," which appears as step (c) in both claims 1 and 2 and would be necessary to apprise one skilled in the art of the scope of the invention. None of the applications provide any description or guidance, as well.

108. Claims 3-7 of the '456 patent depend either directly or indirectly from claim 1 and therefore contain each and every limitation of claim 1, including the recording step. Thus, claims 3-7 also are indefinite.

109. The "recording" step first appeared in a February 22, 2008 Amendment. (Ex. X) No support for that term appears either in the specification of the '359 application, in the Amendments submitted during accelerated examination, or in the updated AES document.

110. The '456 patent, and its predecessor applications, do not provide any means for recording the presence of the JAK2 mutant.

111. Claim 1 is also indefinite under 35 U.S.C. §112, second paragraph, because it refers to two different nucleotide numbers to designate the mutation to be detected in the method. The preamble of claim 1 of the '456 patent refers to nucleotide position "1849" in the JAK2 gene. However, steps (b) and (c) of issued claim 1 refer to nucleotide position "2343" of SEQ ID NO: 2.

112. The '456 patent provides no guidance to the relationship between the nucleotide position "1849" in JAK2 and nucleotide position "2343" in SEQ ID NO: 2 and only adds to the confusion. For example, SEQ ID NO: 2 in the predecessor applications and in the '456 patent is described (incorrectly) as "G1849T mutation in JAK2 gene." SEQ ID NO: 2 represents the genomic DNA (and includes the non-coding region). Thus, the sequence position corresponding

to "1849" (when referring to the JAK2 coding region) is actually "2343" in SEQ ID NO: 2. There are numerous ATG sites in SEQ ID NO: 2, and it is unclear where translation begins.

113. The reference to two different nucleotide numbers in claim 1, in view of the lack of guidance provided in the predecessor applications and in the '456 patent, lacks the clarity necessary to allow a person of ordinary skill to precisely understand what infringes the claim.

114. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as indefinite.

COUNT VII

(Declaration of Invalidity of Claims 1 and 2 of the '456 Patent Pursuant to 35 U.S.C. § 101 for Not Containing Patent-Eligible Subject Matter)

115. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 114, as if set forth in full.

116. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the validity of the claims of the '456 patent. Claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101 for containing patent-ineligible subject matter.

117. Claim 1 of the '456 patent is directed to any *in vitro* method for determining the presence of the G1849T mutation in the JAK2 gene in a human patient comprising three steps. Exhibit A, col. 45, lines 26-34. The three steps include an "obtaining and analyzing" step, a "detecting" step, and a "recording" step. *Id.* at lines 29-34.

118. Claim 2 of the '456 patent is directed to any in vitro method for diagnosing a human patient for an MPD selected from a group of three (3) disorders, wherein the presence of the T mutation at position 2343 of SEQ ID NO:2 indicates the patient has, or is likely to have,

the claimed disorders. *Id.* at lines 35-50. Claim 2 includes the same three steps as claim 1, an "obtaining and analyzing" step, a "detecting" step, and a "recording" step. *Id.* at lines 40-45.

119. Claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc) *cert. granted*, 129 S. Ct. 2735.

120. Claims 1 and 2 are not tied to a particular machine or apparatus. *Id.* at 954.

121. Claims 1 and 2 of the '456 patent do not transform a particular article into a different state or thing. *Id.*

122. The essence of the method for testing for the presence of the mutation or for diagnosing a patient for a MPD is nothing more than a mental process, which involves no transformation of any article into a different state or thing.

123. Bio-Reference is entitled to a declaratory judgment that claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. §101.

COUNT VIII

(Declaration That Ipsogen Has Misused the '456 Patent)

124. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 123, as if set forth in full.

125. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the impermissibility of Ipsogen's market practices of the '456 patent. Ipsogen has committed patent misuse through its attempts to license the '456 patent and its conduct requiring diagnostic laboratories to purchase Ipsogen's JAK2 test kits for commercial purposes, putting those laboratories at risk of violating FDA regulations, in order to practice the claims of the '456 patent.

126. Ipsogen has broadened the scope of the '456 patent impermissibly, resulting in anticompetitive effects.

127. Upon information and belief, Ipsogen broadened impermissibly the scope of '456 patent, by tying its proposed license to the '456 patent to the purchase of its JAK2 kits. As shown in paragraphs 37 to 43, the '456 patent only covers tests that detect and record the presence of the JAK2 mutation. The '456 patent does not cover tests that detect and record **the absence** of the JAK2 mutation.

128. Ipsogen's JAK2 kits constitute a separable, staple good because Ipsogen's JAK2 kits have substantial non-infringing uses. Every use of an Ipsogen JAK2 kit that has a negative result for the JAK2 mutation falls outside the scope of the claims of the '456 patent. .

129. By requiring licensees (through either express or implied licenses) to purchase Ipsogen JAK2 kits to practice the claims of the '456 patent, even when the test does not find the JAK2 gene, Ipsogen has broadened its patent grant through an impermissible tying arrangement.

130. Ipsogen possesses market power in the relevant market for diagnosis of MPD, particularly PV. The only substitute to the claimed methods of the '456 patents for diagnosis of MPD, particularly PV, is a higher cost and more burdensome bone marrow culture test. With its '456 patent, Ipsogen was able to drive this substitute largely out of the market.

131. As a result, Ipsogen has committed *per se* misuse of the '456 patent.

132. Even if Ipsogen has not committed a *per se* patent misuse, its tying efforts and its other licensing efforts constitute patent misuse under a rule of reason.

133. Ipsogen licenses the '456 patent to a large number of clinical diagnostic laboratories.

134. Upon information and belief, Ipsogen's standard licensing terms impose a royalty fee for each JAK2 test run regardless of whether the test detects and records the JAK2 mutation. This licensing practice impermissibly broadens the scope of the '456 patent.

135. Ipsogen possesses market power in the relevant market for clinical diagnosis of MPD, particularly PV.

136. Ipsogen's licensing practices have anticompetitive affects in the market. In the case of its offer to Bio-Reference, Ipsogen proposed a $35 royalty for each JAK2 test run by Bio-Reference. This $35 fee raises the marginal cost of materials for a JAK2 diagnostic test by three to four fold. This cost increase harms diagnostic laboratories, health insurers and patients, as this extracted cost is passed through the payment system.

137. Bio-Reference is entitled to a declaratory judgment that Ipsogen has misused the '456 patent and that the patent is therefore unenforceable.

COUNT IX

(Declaration of Non-Infringement of the '456 Patent)

138. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 137, as if set forth in full.

139. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning whether and to what extent Bio-Reference infringe any claim of the '456 patent. Bio-Reference's JAK2 mutation test does not infringe any valid claim of the '456 patent.

140. Even if deemed valid and enforceable, claims 4-7 of the '456 patent are not infringed, either literally or under the doctrine of equivalents, at least because Bio-Reference does not use hybridization with probes in their testing methods, as required by those claims.

141. Even if the claims of the '456 patent are determined to be enforceable and not to be invalid, Bio-Reference is entitled to a declaratory judgment that its V617F JAK2 test does not infringe, directly or indirectly, either literally or equivalently, claims 4-7 of the '456 patent.

142. Even if the claims of the '456 patent are determined to be enforceable and not to be invalid, Bio-Reference is further entitled to a declaratory judgment that its V617F JAK2 test does not infringe, directly or indirectly, either literally or equivalently, any claim of the '456 patent when it does *not* detect the presence of the V617F mutation in the JAK2 gene of a test sample.

143. Bio-Reference is entitled to a declaratory judgment that it does not infringe claims 4-7 of the '456 patent and that it does not infringe any claim of the '456 patent when Bio-Reference's test for the JAK2 mutation do not detect the presence of a T at the 2343 position of the JAK2 gene.

COUNT X

(Declaration of Relevant Royalty Base if Bio-Reference is Adjudged to Infringe a Valid, Enforceable Claim of the '456 Patent)

144. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 143, as if set forth in full.

145. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen concerning the proper scope of Bio-Reference's testing and/or testing revenues on which Ipsogen can predicate a claim for damages in the event Ipsogen prevails in an action for patent infringement of the '456 patent and the patent is not found invalid.

146. Ipsogen has demanded that Bio-Reference pay an exorbitant royalty for, or purchase an Ipsogen kit in place of, all of Bio-Reference's JAK2 testing.

147. Even if relevant claims of the '456 patent were considered valid and enforceable, all of the claims of the '456 patent only cover tests that detect and record the presence of the

JAK2 mutation. The claims of the '456 patent do not cover any tests that detect and record **the absence** of the JAK2 mutation.

148. Bio-Reference is entitled to a declaratory judgment that Ipsogen only can base or a claim for damages on testing that results in the detection and recording the presence, but not the absence, of the JAK2 mutation.

COUNT XI

(Declaration That Ipsogen's Existing Licensing Agreements and/or Past Sale of JAK2 Kits cannot be Used to Establish Damages)

149. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 148, as if set forth in full.

150. There is an actual controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Ipsogen about whether Ipsogen can rely on its current and past commercial practice with licensees and JAK2 kit purchasers to establish damages owed by Bio-Reference to Ipsogen.

151. Ipsogen demands that Bio-Reference license the '456 patent and/or purchase Ipsogen's JAK2 kits in performing all JAK2 testing. Ipsogen has asserted that these conditions are consistent with its arrangement with other licensees and/or customers.

152. Bio-Reference contends that Ipsogen's existing licenses and JAK2 sales were obtained by misuses of the '456 patent and by marketing its JAK2 kits in violation of the FDA regulations. Because Ipsogen's existing licensee and customer bases were obtained by unlawful conduct, it should be barred from relying on evidence of the same to prove up any damage claim against Bio-Reference.

153. Ipsogen's demands that Bio-Reference use Ipsogen's kits for commercial use despite the fact that the FDA approved those kits only for RUO constitutes a misuse of the '456

patent. Accordingly, Ipsogen has misused the '456 patent as to Bio-Reference and as to other licensees and customers.

154. Ipsogen has marketed its test kits to Bio-Reference and others in violation of FDA regulations.

155. Bio-Reference is entitled to a declaratory judgment that Ipsogen is barred from relying on any evidence of its existing or past license agreements or JAK2 kits sales, to establish a remedy against Bio-Reference because Ipsogen has licensed the '456 patent and marketed its JAK2 kits in an unlawful manner.

COUNT XII

(False and Misleading Advertising Under the Lanham Act, 15 U.S.C. § 1125(a))

156. Bio-Reference incorporates by reference the allegations contained in paragraphs 1 through 155 as if fully set forth herein.

157. On information and belief, Ipsogen has sold its JAK2 test kits to clinical diagnostic laboratories.

158. Ipsogen has required Bio-Reference to purchase its JAK2 test kits even though it knew that Bio-Reference would use the kits for non-research purposes, including clinical diagnostic testing.

159. In offering to sell these kits to Bio-Reference, Ipsogen falsely and misleadingly represents that its kits are FDA approved for clinical diagnostic testing.

160. Ipsogen's JAK2 test kits are not approved for clinical diagnostic testing. Ipsogen's JAK2 test kits are approved solely for RUO.

161. Despite the RUO limitation, upon information and belief, Ipsogen has required clinical diagnostic laboratories that conduct JAK2 testing to purchase its JAK2 test kits. Upon

information and belief, clinical diagnostic laboratories have purchased the test kits from Ipsogen for use in clinical diagnostic testing.

162. Ipsogen has supplied Bio-Reference's competitors with JAK2 test kits sold through false and misleading sales tactics, and false and misleading representations of fact, including implicit misrepresentations that the test kits were FDA approved for clinical diagnostic testing.

163. Ipsogen's false and misleading representations in its commercial advertising misrepresent the nature, characteristic, and quality of the JAK2 test kits, as the kits are not FDA approved for clinical diagnostic testing.

164. Ipsogen's use of false and misleading representations regarding its JAK2 test kits in commerce constitutes unfair competition in violation of 15 U.S.C. § 1125(a). Bio-Reference has suffered and will continue to suffer irreparable injury and damages as a result of Ipsogen's acts.

165. As result, Bio-Reference is entitled to:

(a) Preliminary and permanent injunctive relief enjoining Ipsogen from representing, promoting, marketing, selling, or advertising its JAK2 test kits as FDA approved for clinical diagnostic testing, pursuant to 15 U.S.C. § 1116 and other applicable laws.

(b) An award granting Bio-Reference monetary relief including, but not limited to, all damages caused by Ipsogen's false and/or misleading advertising, Ipsogen's profits, treble damages, and the costs of this action, including reasonable attorneys' fees and prejudgment interest, pursuant to 15 U.S.C. § 1117 and other applicable laws.

PRAYER FOR RELIEF

WHEREFORE, Bio-Reference asks this Court to enter judgment in its favor against defendants as follows:

A. A judgment declaring that the claims of '456 patent are limited to detecting and recording the presence, but not the absence, of the T in the JAK2 gene at position 2343;

B. A judgment declaring that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006;

C. A judgment declaring that claims 1 through 3 of the '456 patent are invalid under 35 U.S.C. §§ 102(b) and/or 102(a);

D. A judgment declaring that claims 1 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description;

E. A judgment declaring that claim 1 and claims 3 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement;

F. A judgment declaring that claims 1 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as indefinite;

G. A judgment declaring that claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101;

H. A judgment declaring that Ipsogen has misused the '456 patent, and the '456 patent is therefore unenforceable;

I. A judgment declaring that Bio-Reference does not infringe any claim of the '456 patent when its JAK2 testing does not detect the JAK2 mutation and a declaratory judgment that Bio-Reference does not infringe claims 4 through 7 of the '456 patent;

J. A judgment declaring that, if Bio-Reference is adjudged to infringe any claim of the '456 patent, Bio-Reference is only liable as to JAK2 testing in which particular tests actually detected and recorded the presence of the JAK2 mutation;

K. A judgment declaring that Ipsogen is barred from relying on evidence of its existing licensing agreement and/or past sale of JAK2 kits to establish a claim for damages against Bio-Reference; and

L. A judgment against Ipsogen for violating the Lanham Act, 15 U.S.C. 1125(a), (i) entering a permanent injunction enjoining Ipsogen from representing, promoting, marketing, selling, or advertising its JAK2 test kits as FDA approved for clinical diagnostic testing, pursuant to 15 U.S.C. § 1116 and other applicable laws; and (ii) granting Bio-Reference monetary relief including, but not limited to, all damages caused by Ipsogen, Ipsogen's profits, treble damages, and the costs of this action, including reasonable attorneys' fees and prejudgment interest, pursuant to 15 U.S.C. § 1117 and other applicable laws.

L. Granting Bio-Reference such other relief as the Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Bio-Reference demands a trial by jury of all matters to which they are entitled to a trial by jury.

Dated: November 25, 2009

Respectfully submitted,

/s/ Michael J. Sullivan

Michael J. Sullivan, Esq.
Mark K. Silver
Coughlin Duffy LLP
350 Mount Kemble Avenue
Morristown, NJ 07962
973-631-6013 (direct dial)
973-267-6442 (fax)
msullivan@coughlinduffy.com
msilver@couglinduffy.com

Of Counsel:
Mark Fox Evens
Jorge A. Goldstein
Byron L. Pickard
STERNE, KESSLER, GOLDSTEIN & Fox P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005
Tel: 202.371.2600
Fax: 202.371.2540

Attorneys for Plaintiff
Bio-Reference Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BIO-REFERENCE LABORATORIES, INC.
481 Edward H. Ross Drive
Elmwood Park, New Jersey 07407

Plaintiff

v.

ASSISTANCE PUBLIQUE – HÔPITAUX DE PARIS
3 Avenue Victoria
Paris, France 75004

and

INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE (INSERM)
101 Rue de Tolbiac
Paris, France 75013

and

INSTITUT GUSTAVE ROUSSY
39 Rue Camille Desmoulins
Villejuif, France 94800

and

UNIVERSITÉ DE VERSAILLES – ST. QUENTIN EN YVELINES
23 Rue Du Refuge
Versailles, France 78035

and

UNIVERSITÉ PARIS-SUD
Batiment 300
15 Rue Georges Clemenceau
Orsay, France 91400

Defendants.

Case No.:

FILED UNDER SEAL

Jury Trial Demanded

COMPLAINT FOR DECLARATORY JUDGMENT AND FOR FALSE AND MISLEADING ADVERTISING

INTRODUCTION

A. The Parties.

Plaintiff Bio-Reference Laboratories, Inc. ("Bio-Reference") is an independent full-service clinical laboratory, with specialty capabilities in oncology and genomics. Through its cancer diagnostics business unit, GenPath, Bio-Reference offers specialized services in pathology, cytogenetics, molecular diagnostics and personalized medicine.

Defendants Assistance Publique – Hôpitaux De Paris, Institut National De La Santé Et De La Recherche Médicale (INSERM), Institut Gustave Roussy, Université De Versailles – St. Quentin En Yvelines, and Université Paris-Sud (collectively, the "Defendants"), through their alleged exclusive licensee Ipsogen S.A. and Ipsogen S.A.'s American subsidiary Ipsogen, Inc. (collectively "the Ipsogens"), threatened Bio-Reference with patent infringement of U.S. Patent No. 7,429,456 ("the '456 patent"), entitled "Identification of a JAK2 Mutation in Polycythemia Vera."

B. Bio-Reference's Unsuccessful Attempts To Negotiate With The Ipsogens.

The Ipsogens contacted Bio-Reference and asserted that Bio-Reference infringed its intellectual property, specifically the '456 patent. Bio-Reference attempted to negotiate a resolution of the dispute with the Ipsogens, believing that the Ipsogens had sufficient interest in the '456 patent because the face of the '456 patent lists "IPSOGEN, Marseilles (FR)" as assignee. The Ipsogens' demands, however, were excessive, particularly in light of serious questions concerning the '456 patent's validity and whether the limited scope of the patent's claims actually covered Bio-Reference's activities. Further, the Ipsogens demanded that Bio-Reference purchase the Ipsogens' diagnostic kits for clinical diagnostic use, an impermissible use under the Federal

Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301, *et. seq.*, because the diagnostic kits are restricted to research use only ("RUO") under the applicable regulations. The Ipsogens' demands that Bio-Reference purchase the kits as the only manner of obtaining a license to the patent also represent an improper tying arrangement because use of the kits far exceeds the limited method claims of the '456 patent. When Bio-Reference refused to put itself in a position to violate federal law, the Ipsogens demanded a license that would have required Bio-Reference to pay exorbitant licensing fees.

C. Bio-Reference Initiates A Declaratory Judgment Action, And The Ipsogens Move To Dismiss.

As a result of the Ipsogens' threats, on November 25, 2009, Bio-Reference filed a declaratory judgment action against the Ipsogens related to the '456 patent in the United States District Court for the District of New Jersey, Case No. 2:09-cv-06017-SRC-MAS, based in part on the fact that "IPSOGEN, Marseilles (FR)" is listed as the assignee on the face of the '456 patent (the "2009 Complaint"). IPSOGEN, Marseilles (FR) is Ipsogen, S.A. Ipsogen, Inc. moved to dismiss that action for lack of subject matter jurisdiction and for failure to join indispensable parties, namely the Defendants, arguing that Bio-Reference should file its action against the French owners of the '456 patent in this Court pursuant to 35 U.S.C. § 293 ("Motion to Dismiss"). In its Motion to Dismiss, Ipsogen, Inc. asserts (i) that Defendants own the '456 patent, despite the '456 patent issuing to Ipsogen S.A., and, therefore, the Defendants are necessary and indispensable parties to any action concerning the '456 patent; (ii) that Ipsogen S.A. and Ipsogen, Inc. are mere licensees to the '456 patent; and (iii) that neither it nor Ipsogen S.A. have sufficient license rights to enforce or defend the '456 patent. That Motion is pending. On February 18, 2010, Ipsogen S.A. entered an appearance in the New Jersey action and joined Ipsogen, Inc.'s Motion to Dismiss.

Before filing its 2009 Complaint, Bio-Reference negotiated in good faith with the Ipsogens, intending to settle any dispute regarding the '456 patent short of litigation. Neither of the Ipsogens negotiated in good faith. Neither of the Ipsogens disclosed their lack of ownership rights. Neither of the Ipsogens disclosed their inability to enforce the '456 patent when threatening litigation. Defendants knew, or should have known, that the Ipsogens were misrepresenting the ownership of the '456 patent to extract exorbitant license terms from Bio-Reference. Defendants knew, or should have known, that the Ipsogens were not negotiating in good faith with Bio-Reference. Defendants knew, or should have known, that the '456 patent incorrectly listed "IPSOGEN, Marseilles (FR)" as the assignee. Defendants' fraud on the United States Patent and Trademark Office ("USPTO") and on Bio-Reference, set forth in Counts XIII and XIV herein, resulted in the filing of this action.

D. Bio-Reference Files The Instant Action.

Because of Defendants' complicity in the Ipsogens repeated threats – threats that the Ipsogens had no basis to make if they were mere licensees without the right to enforce the '456 patent – that Bio-Reference take a license at an exorbitant royalty, buy the Ipsogens' kits, or stop testing, Bio-Reference has been forced to file this Complaint. Bio-Reference seeks judicial declarations from this Court that the claims of the '456 patent, even if assumed valid and enforceable, are limited to detecting and recording "the presence" of a certain gene mutation, but do not cover detecting or recording "the absence" of the gene mutation (Count I), that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006 (Count II), that the '456 patent claims are invalid (Counts III-VII), that Defendants, through the Ipsogens, misused the '456 patent (Count VIII), that Bio-Reference has not infringed the '456 patent (Count IX), that, if Bio-Reference has infringed the '456 patent, the reasonable royalty owed to Defendants should be limited, given the limited scope of its claims (Count X), and that Defendants cannot

rely on the Ipsogens' existing license agreements or sales of its kits as evidence of damages because those licenses and sales violate federal law (Count XI). Bio-Reference also brings a claim against Defendants for the Ipsogens' false and misleading advertising under the Lanham Act, 15 U.S.C. § 1125(a), (Count XII). Additionally, Bio-Reference seeks a judicial declaration that the '456 patent is unenforceable due to inequitable conduct because of knowing misrepresentations to the USPTO that Ipsogen S.A. was the assignee of the '456 patent (Count XIII). Lastly, Bio-Reference seeks a judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 based on the misrepresentations about the Ipsogens' rights under the '456 patent, which forced Bio-Reference to commence this action (Count XIV). In support of this action, Bio-Reference further alleges in detail:

NATURE AND BASIS OF THE ACTION

1. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*, the United States patent laws, 35 U.S.C. §§ 1, *et seq.* and the Lanham Act, 15 U.S.C. § 1125(a). Plaintiff requests judicial declarations of the parties' rights and liabilities with respect to the Defendants' '456 patent. A copy of the '456 patent is attached as Ex. A.

THE PARTIES

2. Plaintiff Bio-Reference is a publicly-traded New Jersey corporation, having its principal place of business at 481 Edward H. Ross Drive, Elmwood Park, New Jersey 07407.

3. Defendant Assistance Publique – Hôpitaux De Paris is a nonresident patentee located in Paris, France, and is an owner of the '456 patent.[1]

4. Defendant Institut National De La Santé Et De La Recherche Médicale (INSERM) is a nonresident patentee located in Paris, France, and is an owner of the '456 patent.

[1] Note that, as shown on the face of the patent, the Defendants are not the assignees of record of the '456 patent. That distinction belongs to "IPSOGEN, Marseilles (FR)".

5. Defendant Institut Gustave Roussy is a nonresident patentee located in Villejuif, France, and is an owner of the '456 patent.

6. Defendant Université De Versailles – St. Quentin En Yvelines is a nonresident patentee located in Versailles, France, and is an owner of the '456 patent.

7. Defendant Université Paris-Sud is a nonresident patentee located in Orsay, France, and is an owner of the '456 patent.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35 of the United States Code, and under the Lanham Act, 15 U.S.C. §1125(a).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1332, and 1338, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. As shown herein, a justiciable case or controversy exists between the parties that is ripe for this Court's adjudication.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and 35 U.S.C. § 293.

11. This Court has personal jurisdiction over the Defendants pursuant to 35 U.S.C. § 293. This Court has jurisdiction to take any action respecting the '456 patent or rights thereunder that it would have if the Defendants were personally within the jurisdiction of the Court. Upon information and belief, the Defendants do not reside in the United States, nor have the Defendants filed with the USPTO a written designation stating the name and address of a person residing in the United States on whom may be served process or notice of proceedings affecting the patent or rights thereunder.

STATEMENT OF FACTS

A. COGNIZABLE CASE OR CONTROVERSY EXISTS BETWEEN DEFENDANTS AND BIO-REFERENCE CONCERNING BIO-REFERENCE'S JAK2 DIAGNOSTIC TESTING.

1. The JAK2 Mutation.

12. In the Spring of 2005, several independent teams of researchers separately published papers reporting the identification of the JAK2 V617F genetic mutation ("JAK2 mutation")[2] that was present in a majority of patients with certain types of myeloproliferative disorders ("MPD"). MPD is a group of conditions that cause blood cells – platelets, white blood cells, and red blood cells – to grow abnormally in the bone marrow. For one particular MPD, Polycythemia Vera ("PV"), a particularly high percentage of diagnosed patients carried the JAK2 mutation.

13. These discoveries potentially presented a new means for diagnosing MPD, especially PV, by genetically screening patients for the mutation.

14. Prior to these discoveries, the standard way to diagnose the condition biologically was to culture patient bone marrow tissue. This procedure was labor-intensive and burdensome on patients.

15. After reading these independent reports, Bio-Reference, through its cancer diagnostics unit, GenPath, developed and marketed a JAK2 diagnostic test in March 2006.

2. The Ipsogens' Contacts With Bio-Reference.

16. On January 9, 2007, Ipsogen S.A. sent a letter directed to Bio-Reference's "Legal Department" with the reference line:

---

[2] "JAK2 V617F" identifies a genetic mutation using a conventional nomenclature known to biologists. In this case "JAK2" identifies a particular gene that codes for a tyrosine kinase protein. "V617F" identifies that a substitution of valine ("V") amino acid to phenylalanine ("F") amino acid occurred at position 617 of the JAK2 amino acid sequence for tyrosine kinase.

Re: Use of JAK2 V617F mutation technology in Myeloproliferative Disorders

Patent Estate: Patent Application US10/580,458 filed October 26, 2005.[3]

(Ex. B)

17. In the letter, Ipsogen S.A. represented that it was "the exclusive licensee of intellectual property rights that relate to JAK2 V617F mutation technology" that "cover a number of territories including USA." The letter continued, "Our research indicates that you are using or could be interested in using this technology rather than purchasing the Ipsogen Kit product and wish [SIC] to ascertain whether you may require a license under our intellectual property." The letter enclosed a technology brief and a table summarizing licensing terms. The Technology Brief stated that Ipsogen S.A.'s offer was open until January 31, 2007. The technology brief also identifies Ipsogen S.A. as having a Connecticut office.

18. Shortly after receiving the January 9, 2007 letter, Bio-Reference received a follow-up telephone call on the Ipsogens' behalf. The individual placing the call to Bio-Reference could not answer Bio-Reference's basic questions about the Ipsogens' intellectual property, such as proof that the Ipsogens owned or had rights to the intellectual property, and would not confirm whether she was employed by either Ipsogen, S.A. or Ipsogen, Inc.

19. Two follow-up emails from the Ipsogens, dated January 17, 2007, and January 19, 2007, provided a copy of proposed license terms, a copy of the published US10/580,458 patent application and URL links to press releases indicating the Ipsogens had acquired an interest in a pending patent application directed to the JAK2 mutation. (Exs. C & D)

---

[3] The US10/580,458 patent application did not result in the '456 patent.

20. After receiving these emails, Bio-Reference considered the information but did not hear back from the Ipsogens until the middle of 2008.

21. On May 15, 2008, the Ipsogens' Vice President Susan Hertzberg sent an email to Bio-Reference stating:

> I have made several attempts at contact with your company but have been unable to get a response.
>
> You may be aware that **Ipsogen** is the exclusive licensee of intellectual property rights that relate to JAK2 V617F mutation technology. **Our patent** issued in the EU in 2007 and **we** have accelerated prosecution status with the [United States Patent and Trademark Office][4]....
>
> ****
>
> We have already granted a small number of non-exclusive licenses under our [JAK2] intellectual property rights and do not expect to continue much longer with this option. **This will be our last attempt to contact you for this purpose**.
>
> If we do not hear from you **before June 15, 2008** we will conclude a lack of interest on your part in licensing rights to perform testing. Should our US patent grant, we will expect that Bio Reference will respect our intellectual property rights and immediately stop all JAK2 in-house testing by means other than Ipsogen Kits.

(Ex. E) (boldface emphasis in original; underlined emphasis added)

22. On April 30, 2009, the Ipsogens again wrote to Bio-Reference enclosing the cover page of the '456 patent[5] stating that Bio-Reference "is using the JAK2 V617F mutation technology for clinical diagnostic use." (Ex. F) The cover page identifies "IPSOGEN Marseilles (FR)" as the assignee. The letter closed, "We look forward to providing your lab with an appropriate solution that will meet your current and future needs while respecting our intellectual property . . . you will shortly be contacted by an Ipsogen Regional Territory Manager."

---

[4] Hereafter "USPTO."

[5] The '456 patent issued on September 30, 2008.

(emphasis added) At the bottom of the Ipsogen's letter, is printed "Ipsogen, Inc." with a Connecticut address and Ipsogen, S.A. with a Marseilles, France address. The letterhead states "IPSOGEN Cancer Profiler." *See* ¶ 79, *infra*, and Ex. R.

23. In that letter, the Ipsogens suggested that Bio-Reference purchase JAK2 diagnostic kits. The JAK2 kits are not authorized for any use other than RUO. Bio-Reference cannot legally use these kits for clinical diagnostic testing. 21 C.F.R. 809.10(c)(2)(i). The Ipsogens knew Bio-Reference engaged in clinical diagnostic testing. To resolve the dispute, the Ipsogens effectively demanded that Bio-Reference violate federal law.[6]

24. No Ipsogen Regional Territory Manager ever contacted Bio-Reference, despite the Ipsogens' representation in its April 30, 2009 letter that such contact would occur.

25. On August 3, 2009, Foley & Lardner ("Foley"), identifying Foley as counsel for "Ipsogen S.A.", wrote to Bio-Reference's CEO requesting that Bio-Reference "consider the claims [of the '456 patent] in view of the attached document found on the web site of your business unit GenPath." (Ex. G) The same Foley lawyer, who signed that letter, prosecuted the '456 patent. (*See* Section D., *infra*, paragraphs 46-61 and Section E, *infra*, paragraphs 62-71)

26. Shortly thereafter, Bio-Reference's CIO responded to this letter with an email stating, "We would like to work out some reasonable arrangement with Ipsogen for resolution rather than drag things on with further investigation [of Ipsogen's claims]. . . . We are confident the matter can be resolved." (Ex. H)

27. On August 19, 2009, the Ipsogens' attorney responded, offering terms that required Bio-Reference to cease its own JAK2 testing and to conduct future in-house testing only by purchase and use of the Ipsogens' JAK2 test kits:

---

[6] *See* ¶¶ 72-81, *infra*.

> If [Bio-Reference] elects to conduct its own JAK2 tests, [Bio-Reference] must buy JAK2 test kits from Ipsogen and validate the assay as necessary.

(Ex. I)

28. The Ipsogens offered the JAK2 kit to Bio-Reference at a price of [redacted] per kit. By comparison, the material costs for Bio-Reference's in-house assay total about ten dollars.[7]

29. On August 25, 2009, outside counsel for Bio-Reference responded to the August 19, 2009 letter, stating that Bio-Reference would respond following an evaluation of Bio-Reference's activities, the '456 patent, and the license terms proposed by the Ipsogens. (Ex. J)

30. The next day, the Ipsogens' attorney wrote back stating: "Ipsogen does not authorize Bio-Reference to run [its in-house JAK2] assay covered by the claims of U.S. Patent No. 7,429,456. Instead, Ipsogen expects Bio-Reference to stop any such activity." (Ex. K)

31. For the next several months, the parties and their respective counsel communicated concerning their differences over JAK2 testing and the '456 patent. As part of those communications, Bio-Reference advised the Ipsogens of its view that the claims of the '456 patent were invalid and were not infringed by Bio-Reference's JAK2 testing.

32. The Ipsogens demanded access to Bio-Reference's sensitive business information reflecting JAK2 testing volumes. Bio-Reference responded that it first required a confidential non-disclosure agreement.

33. On October 30, 2009, the Ipsogens sent Bio-Reference an e-mail that attached a confidentiality agreement, demanding:

> If we do not have the signed [confidentiality] agreement and JAK2 data by the end of day today, we will consider that a sign of your unwillingness to cooperate with us on this matter and will expect

---

[7] Pending disposition of a Motion For Leave to File Under Seal, Bio-Reference has redacted certain portions of this Complaint in order to protect what defendants may deem to be confidential information.

> that you will immediately start sending your JAK2 testing to an authorized provider. If you do not send your JAK2 testing out at that point, we will proceed with next steps to protect our intellectual property.

(Ex. L) (emphasis added)

34. On November 6, 2009, Bio-Reference confidentially provided the JAK2 test volume data to the Ipsogens, but reminded the Ipsogens of Bio-Reference's position that any act alleged to have been an infringement of the '456 patent could not include detecting the "absence" of the mutation (*i.e.*, a negative result). Bio-Reference reminded the Ipsogens that, during prosecution, the Ipsogens had expressly cancelled the term "the absence" that appeared in the original claims during prosecution to overcome rejections by the USPTO.

35. On November 10, 2009, the Ipsogens sent an email to Bio-Reference, attaching a proposed sublicense:

> Attached please find the Ipsogen [redacted] Sublicense Agreement for JAK2.
>
> [redacted]
>
> You will have until November 30, 2009 to execute this agreement. If it is not executed prior to this date, we expect you to send your JAK2 testing to an authorized provider.

(Ex. M) (emphasis added)

36. The Ipsogens' proposed [redacted] sublicense requires Bio-Reference to pay a [redacted] The Look-Back fee represents a trebling of the $35 running royalty fee. The trebling demonstrates the Ipsogens' arrogance in dealing with Bio-

Reference, dictating overreaching terms for a patent with limited scope and of questionable validity and enforceability. In exchange for the license, Bio-Reference only receives a one-year, non-exclusive sublicense and a release of any claim against Bio-Reference for its alleged violation of the Ipsogens' patent rights.

37. This proposed sublicense requires Bio-Reference to pay [redacted] to the Ipsogens for all JAK2 tests irrespective of whether the test detected and recorded the presence or the absence of the mutation. As explained more fully in paragraphs 41 to 45, the '456 patent claims are limited to detecting and recording only the presence of a JAK2 mutation; the claims do not cover detecting and recording the absence of the mutation.

38. In response to the November 11, 2009 ultimatum, Bio-Reference filed the 2009 Complaint and now initiates this case.

B. THE '456 PATENT.

39. On September 30, 2008, the USPTO issued the '456 patent, listing "IPSOGEN, Marseilles (FR)" as the assignee. The '456 patent issued with seven claims.

40. The '456 patent relates to the JAK2 mutation, which it refers to as the "V617F variant" of JAK2 (*see, e.g.*, Ex. A, Abstract) or alternatively, the "JAK2 G1849T variant"[8] (*see, e.g.*, Ex. A, col. 4, lines 35-40). According to the '456 patent, the detection of the "V617F variant" of JAK2 in a sample from a human patient is associated with certain MPD, such as PV. *See, e.g.*, Ex. A, Abstract.

---

[8] Whereas "JAK2 V617F" identifies a mutation based on the sequence of amino acids for which it coded (see footnote 1 above), "JAK2 G1849T" identifies the same mutation based on a corresponding DNA sequence. "JAK2" identifies a particular gene that codes for a tyrosine kinase enzyme. "G1849T" identifies that at position 1849 of the JAK2 DNA coding sequence, guanine ("G") was substituted for thymine ("T").

C. THE '456 PATENT CLAIMS ARE LIMITED TO CLAIMING THE DETECTION AND RECORDATION ONLY OF THE PRESENCE, BUT NOT THE ABSENCE, OF THE JAK2 MUTATION.

41. Notably absent from the claims of the '456 patent are steps for detecting and recording the "absence" of the T in the JAK2 mutation. Ipsogen deliberately deleted the term "absence" from the claims to obtain USPTO approval for the '456 patent, as shown below.

42. Independent claims 1 and 2 as they appear in the '456 patent read (emphasis added):

> 1. An in vitro method to determine **the presence** of the G1849T mutation in the JAK2 gene in a human patient comprising:
>
> a) obtaining and analyzing a nucleic acid sample from the human patient;
>
> b) detecting a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample; and
>
> c) **recording the presence** of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample.
>
> 2. An in vitro method to determine if a human patient is currently suffering from or is likely to develop a myeloproliferative disorder selected from the group consisting of Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis comprising:
>
> a) obtaining and analyzing a nucleic acid sample from the human patient;
>
> b) detecting a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample; and
>
> c) **recording the presence** of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample;
>
> wherein the presence of a T at position 2343 of SEQ ID NO 2 indicates the human patient is currently suffering from or is likely to develop a myeloproliferative disorder selected from the group consisting of Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis.

43. However, as originally filed, in Application Number 11/934,359, independent claims 1, 17, and 20, were as follows (emphasis added):

> 1. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop a myeloproliferative disorder, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder.
>
> 17. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop the myeloproliferative disorder myelofibrosis, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder.
>
> 20. A method to determine the presence **or absence** of the G1849T variant of the JAK2 gene in a patient suffering from or likely to develop a myeloproliferative disorder, comprising: detecting the presence **or absence** of the G1849T variant of the JAK2 gene in a nucleic acid sample from the patient, wherein the presence of the G1849T variant of the JAK2 gene indicates a myeloproliferative disorder, wherein the nucleic acid sample is mRNA, and comprising amplifying by reverse transcriptase-polymerase chain reaction.

(Ex. N)

44. The USPTO issued a Final Office Action on May 29, 2008, rejecting the proposed claim language. (Ex. O) To overcome the rejections, Foley, as patent prosecution counsel, amended the claims as follows (arrows showing the deleted language have been added for emphasis):

1. (Currently Amended) An *in vitro* method to determine the presence ~~or absence~~ of the V617F mutation in the JAK 2 gene, wherein the mutated JAK 2 gene is SEQ ID NO: 2, from a human patient, comprising:

analyzing a nucleic acid sample from the human patient, detecting the presence ~~or~~ ~~absence~~ of the V617F mutation in the JAK 2 gene in the nucleic acid sample from the human patient and recording the presence ~~or absence~~ of the mutation in the sample from the human patient, wherein the presence of the mutation in the JAK 2 gene in the sample indicates a myeloproliferative disorder in said human patient selected from Polycythemia Vera, essential thrombocythemia, and idiopathic myelofibrosis.

(Ex. P)

45. On August 12, 2008, the USPTO mailed a Notice of Allowance and Examiner's Amendment, canceling and rewriting two independent claims as they would later issue as claims 1 and 2 in the '456 patent. (Ex. Q)

D. THE '456 PATENT WAS FRAUDULENTLY PROCURED FROM THE USPTO

46. During the prosecution of the '456 patent, fraudulent misrepresentations were made intentionally to the USPTO.

47. Foley are the attorneys responsible for prosecuting the application that resulted in the '456 patent.

48. On September 3, 2008, Foley submitted an Issue Fee Transmittal Form to the USPTO. *See* Fee Transmittal Form attached as Ex. Y. That form lists "IPSOGEN" as the assignee and "Marseilles, France" as its residence. *Id.*

49. As a result of the submission of the Issue Fee Transmittal Form, the '456 patent issued on September 30, 2008 with "IPSOGEN, Marseilles (FR)" listed as the assignee.

50. The same Foley attorney who signed and filed the USPTO's Patent Assignment Recordation form for the assignments and the license of the '456 patent, also signed the Issue Fee Transmittal Form that incorrectly lists "IPSOGEN" as the assignee and "Marseilles, France" as

its residence. Foley knew that Ipsogen S.A. was not the assignee when it signed and submitted the Issue Fee Transmittal Form to the USPTO.

51. In its Motion to Dismiss, filed in the New Jersey action, Ipsogen, Inc. contends that Defendants own the '456 patent, that Defendants licensed the '456 patent to the Ipsogens, but that Defendants did not assign the '456 patent to Ipsogen S.A. A Foley attorney signed that Motion to Dismiss and signed Ipsogen S.A.'s Notice of Joinder to that motion.

52. If the Ipsogens' representations are true, including those set forth in their Motion to Dismiss, then the representation made in the Issue Fee Transmittal Form that Ipsogen S.A. was the assignee was false when made. Both representations are mutually inconsistent. Both representations were signed by the same law firm, Foley. The same Foley attorney who prosecuted the '456 patent before the USPTO also represented the Ipsogens in negotiations with Bio-Reference. And, Foley is counsel of record for Ipsogen, Inc. and Ipsogen S.A. in the New Jersey action.

53. If the Ipsogens' representations are true, including those set forth in their Motion to Dismiss, then the Ipsogens and the Defendants had to know that the Ipsogens were mere licensees and that Ipsogen S.A. was not an assignee at the time that Foley filed the Issue Fee Transmittal Form with the Office, particularly as signatories to the license agreement.

54. On June 5, 2008, Foley filed an assignment of the '456 patent from all five of the Defendants to three entities, including Assistance Publique – Hôpitaux De Paris, Institut National De La Santé Et De La Recherche Médicale (INSERM), and Institut Gustave Roussy R&D. (Ex. Z)

55. Also on June 5, 2008, Foley filed the conveyance of a license under the '456 patent from the three entities in paragraph 54: Assistance Publique – Hôpitaux De Paris, Institut

National De La Santé Et De La Recherche Médicale (INSERM), and Institut Gustave Roussy R&D to IPSOGEN S.A. (Ex. Z)

56. Foley and Defendants caused the '456 patent to issue with the face of the patent incorrectly stating "IPSOGEN, Marseilles (FR)" as the assignee, even though Ipsogen, Inc. stated in its Motion to Dismiss that Ipsogen S.A. is only a licensee.

57. The incorrect listing of Ipsogen S.A. as assignee defeated the public notice function of the patent by allowing the '456 patent to knowingly issue to an incorrect owner.

58. Upon information and belief, as of February 19, 2010, no one has notified the USPTO that the '456 patent incorrectly lists "IPSOGEN, Marseilles (FR)" as the assignee.

59. Upon information and belief, as of February 19, 2010, no one has taken the necessary steps to correct the name of the assignee on the face of the '456 patent.

60. On June 25, 2009, U.S. Appl. No. 12/234,616 ("the '616 application"), which is a child of the '456 patent, was published by the USPTO as U.S. Pub. No. 2009/0162849 A1, listing "IPSOGEN" as the assignee. (Ex. AA)

61. Upon information and belief, as of February 19, 2010, no one has taken the necessary steps to correct the publication of the '616 application.

E. DEFENDANTS ALLOWED THE IPSOGENS' FRAUDULENT MISREPRESENTATION OF THEIR OWNERSHIP RIGHTS IN THE '456 PATENT TO BIO-REFERENCE

62. Defendants knew or should have known that the Ipsogens fraudulently represented to Bio-Reference that the Ipsogens had "intellectual property rights" that were "enforceable" against Bio-Reference. These misrepresentations caused Bio-Reference to commence a declaratory judgment lawsuit in New Jersey relating to the '456 patent.

63. Yet, according to the Ipsogens' Motion to Dismiss, neither of the Ipsogens ever had enforceable "intellectual property rights" related to the '456 patent.

64. Defendants knew or should have known that the Ipsogens threatened to enforce the '456 patent in an infringement action against Bio-Reference in an effort to extract an exorbitant license.

65. Beginning in January 2007, the Ipsogens demanded that Bio-Reference license the '456 patent or purchase the Ipsogens' JAK2 test kits for commercial purposes despite the fact that the Ipsogens' JAK2 test kits are limited to research use only by the FDA.

66. In May 2008, the Ipsogens demanded that Bio-Reference halt all JAK2 in-house testing conducted by any means other than the Ipsogens' JAK2 test kits.

67. The Ipsogens made clear that they would enforce their "intellectual property rights" in the '456 patent if Bio-Reference refused to license the patent, or purchase the test kits from the Ipsogens.

68. The Ipsogens did not disclose their lack of ownership rights when seeking to license the patent to Bio-Reference or when threatening litigation to enforce the '456 patent, a threat that the Ipsogens could not make in good faith.

69. Through their misrepresentations, the Ipsogens intended Bio-Reference to conclude that the Ipsogens could and would commence a suit for infringement of the '456 patent against it.

70. The Ipsogens' threats, coupled with the fraud committed on the USPTO, led Bio-Reference to file the related 2009 Complaint (*i.e.*, declaratory judgment action in the District of New Jersey) and the instant action in the District of Columbia.

71. But for Defendants' sanctioning of the Ipsogens' fraudulent misrepresentations to Bio-Reference and but for the fraud committed on the USPTO, Bio-Reference would not have filed the action in New Jersey.

F. THE IPSOGENS' JAK2 TEST KITS CANNOT BE SOLD FOR CLINICAL DIAGNOSTIC TESTING

72. The Ipsogens market a line of JAK2 test kits under variants of the brand names MutaSearch™, MutaQuant™ and MutaScreen™. These kits qualify as medical devices and are regulated by the FDA under the FDCA. 21 U.S.C. § 321(h).

73. The FDCA sets forth labeling requirements for medical devices and prohibits the selling of misbranded medical devices in interstate commerce. 21 U.S.C. § 331(a). A device is misbranded if its labeling or advertising is false or misleading in any manner. 21 U.S.C. §§ 352(a), 352(q)(l).

74. Certain formal requirements apply to device labeling, and a failure to comply with any of those requirements renders the device misbranded. 21 U.S.C. §§ 352(b), 352(c), 352(e)(2); *see* also 21 C.F.R. §§ 801.1-801.6, 801.15.

75. Medical devices are considered misbranded if they are marketed in interstate commerce before complying with the FDA 510(k) pre-notification requirements or obtaining pre-market approval from the FDA. *See* 21 U.S.C. § 331(r); 21 U.S.C. § 331 (o).

76. The Ipsogens are only authorized to market the JAK2 test kits for RUO. 21 U.S.C. § 352. RUO devices must be labeled and advertised as such. 21 C.F.R. § 809(c)(2)(i). Labeling or advertising an RUO for other uses, such as clinical diagnostic uses, is prohibited. 21 U.S.C. §331(k).

77. Upon information and belief, the Ipsogens sell JAK2 V617F molecular products for screening and monitoring of MPD for clinical diagnostic purposes, even though such products are approved only for RUO. Upon information and belief, the Ipsogens have not complied with the pre-notification requirements, nor have the Ipsogens received any pre-market approval for the JAK2 kits for commercial use.

78. On April 30, 2009, the Ipsogens' Vice President of Sales, North America, Thomas D. Bartel, sent Bio-Reference a letter stating, "Our research indicates that your organization is using the JAK2 V617F mutation technology for clinical diagnostic use (non research activities)" and continues, "Ipsogen currently offers a comprehensive range of JAK2 V617F molecular products for the screening and monitoring of myeloproliferative disorders," including:

> • JAK2 MutaScreen (ref.MSPP-01, MSPP-02), a simple and accurate PCR kit to assess the presence of the mutation in MPD's suspected subjects
>
> • JAK2 MutaScreen + reference scale (ref. MSPP-03), a semi-quantitative real time PCR kit to estimate the mutation load in MPD's diagnosed patients
>
> • JAK2 V617F MutaQuant (ref.MQPP-01), a sensitive and quantitative real-time PCR kit for the monitoring of the mutation load in MPD's diagnosed patient.

(Ex. F)

79. Bio-Reference declined to purchase the Ipsogens' diagnostic kits because of, in large part, the RUO restriction. On June 18, 2009, Mr. Bartel again offered Bio-Reference the same RUO-approved JAK2 kits, despite knowing that Bio-Reference engages in commercial activities. (Ex. R) In his letter, Mr. Bartel advised Bio-Reference "that Ipsogen is the worldwide exclusive owner of intellectual property rights covering JAK2 V617F mutation technology. The cover page of our US patent number 7,429,456, is enclosed for your reference." — language similar to that used in his April 30 letter and on the same stationery with both Ipsogen entities referenced. *See* ¶ 22, *supra*.

80. On August 19, 2009, the Ipsogens' counsel demanded that Bio-Reference stop conducting its own clinical testing for JAK2 unless Bio-Reference "buy[s] JAK2 test kits from Ipsogen . . . ." (Ex. I) The Ipsogens knew that Bio-Reference engages in commercial activities and that the kit has the RUO limitation.

81. Upon information and belief, the Ipsogens' misconduct is not isolated to Bio-Reference. Upon information and belief, the Ipsogens have required other clinical diagnostic labs that conduct JAK2 testing to purchase the JAK2 test kits.

COUNT I

(Declaration that the Claims of the '456 Patent do not Encompass Detecting the Absence of the JAK2 Mutation)

82. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 81, as if set forth in full.

83. The meaning of the claims of the '456 patent constitutes an actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, between Bio-Reference and the Defendants. If the '456 patent is found valid and infringed, then the meaning of the claim terms of the '456 patent will be important to calculating past and future damages for infringement.

84. The Ipsogens, as exclusive licensees and agents of Defendants, asserted to Bio-Reference that the claims of the '456 patent cover Bio-Reference's test results regardless of whether the particular test detects the presence or the absence of the JAK2 mutation, *i.e.*, the presence or absence of a "T in the JAK2 gene at the 2343 position."

85. In turn, Bio-Reference has repeatedly disputed the Ipsogens' overbroad construction of the claims of the '456 patent, contending that the '456 patent claims, if valid, are limited to detecting and recording only the presence of a "T in the JAK2 gene at the 2343 position."

86. At the time the '456 patent issued, and to this date, a person of ordinary skill in the art, would have understood and would understand that the claims of the '456 patent encompass detecting and recording the presence, but not the absence, of a "T in the JAK2 gene at the 2343 position."

87. In any event, Defendants are estopped from asserting that the '456 patent claims include detecting and recording the absence of the T in the JAK2 gene at position 2343 because, during prosecution, to overcome a rejection of its original claims, those claims were amended by deleting the term "or absence" from its proposed phrase "detecting the presence or absence." Accordingly, Defendants deliberately relinquished the noted subject matter during prosecution. *See* ¶¶ 41-45, *supra*.

88. Bio-Reference is entitled to a declaratory judgment that the claims of the '456 patent encompass only detecting and recording the presence of the T in the JAK2 gene at position 2343, but do not include detecting and recording the absence of the T in the JAK2 gene at position 2343.

COUNT II

(Declaration That the Claims of the '456 Patent are Entitled to a Priority Date No Earlier Than May 24, 2006)

89. Bio-Reference incorporates the allegations contained in paragraphs 1-88, as if set forth in full.

90. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Defendants concerning the priority date to which the claims of the '456 patent are entitled. The claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006.

91. The '456 patent was filed as U.S. Appl. No. 11/934,359 on November 2, 2007 ("the '359 application"), as a divisional of U.S. Appl. No. 10/580,458, filed May 24, 2006 ("the '458 application"), which was the national stage entry of PCT Appl. No. PCT/EP05/55586, filed October 26, 2005 ("the '586 PCT application"), which claims foreign priority to French Appl. No. 0411480, filed October 27, 2004 ("the '480 FR application").

92. The '359 application was submitted to the USPTO under "accelerated examination." Two requirements for accelerated examination are the Applicants' submission of a preexamination search statement and an accelerated examination support ("AES") document. The Manual of Patent Examining Procedure (the "MPEP")[9] requires that the AES document include an Information Disclosure Statement ("IDS") citing each reference deemed most closely related to the subject matter of each claim. MPEP 708.02(I)(1). The AES document must include a showing of where each limitation of the claims finds support in the present specification, as well as in applications where priority benefit is being claimed, under 35 U.S.C. § 112, first paragraph, as required by MPEP 708.02(I)(5).[10]

93. Under the Patent Act and the MPEP rules, claims 1-7 of the '456 patent are not entitled to a filing date earlier than that of the '458 application, which was filed May 24, 2006, because neither the '586 PCT application nor the '480 FR application disclose every limitation of claim 1 in the manner required by 35 U.S.C. § 112, first paragraph.

94. First, neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for the claim term "recording the presence of a T in the JAK2 gene," recited in claims 1 and 2 of the '456 patent. The updated AES document submitted on April 21, 2008, was required specifically to show support for every limitation in the claims (original and amended) (Ex. S), but the Ipsogens provided no support in the '586 PCT application or the '480 FR application for "recording the presence or absence of the mutation . . . ". Under 35 U.S.C. §§

---

[9] Published by the USPTO, the MPEP instructs patent examiners on the practices of procedures for examination of a patent application.

[10] For any amendment to the claims that is not encompassed by the initial AES document, applicant is required to provide an updated AES document that encompasses the amended or new claims at the time of filing the amendment. *See* MPEP 708.02(a)(IV).

119, 120 and 365, claims 1-7 of the '456 patent are not entitled to the priority date of either application.

95. The lack of support in the updated AES document is notable because in his March 21, 2008 communication, the Examiner expressly stated that this limitation was not addressed in the original AES document. Furthermore, on page 7 of the Final Office Action dated May 29, 2008, the Examiner stated that "review of the [Applicants'] cited parts of the parent specification and text searching *failed to reveal the support for recording*." (emphasis added).

96. Second, neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for the claim term "detecting, a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample," used in the '456 patent claims. (emphasis added). The preamble of claim 1 of the '456 patent refers to nucleotide position "1849" in the JAK2 gene, while steps (b) and (c) refer to nucleotide position "2343" of SEQ ID NO: 2. Thus, issued claim 1 refers to two different nucleotide numbers to designate the mutation in the JAK2 gene.

97. Step (b) of issued claim 1 recites: "detecting a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample." (emphasis added). Neither the '586 PCT application nor the '480 FR application provides explicit or implicit support for this step because the applications refer only to the JAK2 variant as either "V617F," or alternatively, the "g/t mutation at position 1849 hereinafter called G1849T starting from the ATG marking the start of translation."

98. The only possible support for a T at position 2343 of SEQ ID NO: 2 is the sequence listing. However, the sequence listing itself does not provide guidance as to the relationship between G1849T and a T at position 2343 of SEQ ID NO: 2. For example, SEQ ID NO: 2 in both applications are described (incorrectly) as "G1849T mutation in JAK2 gene."

99. Moreover, SEQ ID NO: 2 represents the genomic DNA (and includes the non-coding region), thus, the sequence position corresponding to "1849" (when referring to the JAK2 coding region) is actually "2343" in SEQ ID NO: 2. As there are numerous ATG sites in SEQ ID NO: 2, it is unclear where translation begins and can only be ascertained by cross-referencing the amino acid sequence of SEQ ID NO: 1.

100. Bio-Reference is entitled to a declaratory judgment that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006.

COUNT III

(Declaration of Invalidity of Claims 1-3 of the '456 Patent Under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 102(a))

101. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 100, as if set forth in full.

102. An actual controversy exists between Bio-Reference and the Defendants, within the meaning of 28 U.S.C. §§ 2201 and 2202, concerning the validity of the claims of the '456 patent.

103. Claims 1-3 of the '456 patent are invalid under 35 U.S.C. §§ 102(a) and/or 102(b).

104. 35 U.S.C. § 102(a) provides (or provides in pertinent part):

> A person shall be entitled to a patent . . . unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

105. 35 U.S.C. § 102(b) provides (or provides in pertinent part):

> A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . .

106. Because the earliest possible filing date to which the claims of the '456 patent can claim benefit is that of the parent application, Appl. No. 10/580,458, filed on May 24, 2006, any reference published before May 24, 2006, is eligible as intervening prior art under 35 U.S.C. § 102.[11]

107. The following printed publications qualify as invalidating prior art as to claims 1-3 of the '456 patent under 35 U.S.C. §§ 102(a) & (b): Baxter, E.J. et al., Lancet 365:1054-1061 (March 19, 2005) ("Baxter") (Ex. T); Levine, R.L. et al., Cancer Cell 7:387-397 (published online March 24, 2005)) ("Levine") (Ex. U); Kralovics, R. et al., N. Engl. J. Med. 352:1779-1790 (April 28, 2005) ("Kralovics") (Ex. V); and Zhao, R. et al., J. Biol. Chem. 280:22788-22792 (published online April 29, 2005) ("Zhao") (Ex. W).

108. Baxter, Levine, Kralovics or Zhao disclose each and every limitation of claims 1-3 of the '456 patent, arranged the same way as in the claims.

109. Baxter, Levine, Kralovics, and Zhao were published between March 19, 2005, and April 29, 2005, more than one year before the May 24, 2006 filing date of the '458 application. Therefore, Baxter, Levine, Kralovics, and Zhao qualify as intervening prior art under 35 U.S.C. § 102(b).

110. Alternatively, even if the Defendants somehow establish that the '456 patent should be entitled to the filing date of the '586 PCT application, October 25, 2005, then Baxter, Levine, Kralovics, and Zhao still qualify as intervening prior art under 35 U.S.C. § 102(a).

111. Therefore, claims 1-3 are invalid under 35 U.S.C. §§ 102(b), or at least 102(a), as being anticipated by each of Baxter, Levine, Kralovics, or Zhao.

---

[11] Count II establishes that the correct priority date for the '456 patent is May 24, 2006, and not either October 26, 2005 (the filing date of the '586 PCT application) or October 27, 2004 (the filing date of the French '480 application),

112. Bio-Reference is entitled to a declaratory judgment that claims 1-3 of the '456 patent are invalid pursuant to 35 U.S.C. §§ 102(a) and/or 102(b).

COUNT IV

(Declaration of Invalidity of Claims 1-7 of the '456 patent Under 35 U.S.C. § 112, First Paragraph, for Lack of Written Description)

113. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 112, as if set forth in full.

114. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning the validity of the claims of the '456 patent. Bio-Reference seeks a declaratory judgment from this Court that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

115. 35 U.S.C. § 112, first paragraph, provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

116. The specification of the '456 patent and applications through which it claims priority do not describe the detecting and recording steps that appear in claims 1 and 2 of the '456 patent. Claims 3-7 of the '456 patent depend either directly or indirectly from claim 1. Therefore, claims 3-7 contain each and every limitation of claim 1. The "detecting" and "recording" steps are such limitations. Thus, the Ipsogens failed to provide a description of dependent claims 3-7 as well.

117. The Defendants cannot rely upon the originally filed claims as evidence that the inventors possessed the invention of claims 1-7 of the '456 patent. The recording step did not

appear originally in the '359 application, but was added to the claims by amendment on February 22, 2008, four months after the November 2, 2007 filing date for the '359 application. (Ex. X) The specification that ultimately appears in the '456 patent first appeared in the '359 application and contains no description about the recording steps.

118. The detecting step was added to the claims at a later date during prosecution of the '456 patent, by the August 12, 2008 Examiner's Amendment. Prior to the Examiner's Amendment, independent claim 1 referred to "detecting the presence of the V617F mutation in the JAK2 gene" in the nucleic acid sample from the human patient. (Ex. P)

119. Even as of the most recent filing date of November 2, 2007, for the '359 application, one of ordinary skill in the art would not have understood the Defendants to be in possession of the full scope of the claimed invention.

120. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description.

COUNT V

(Declaration of Invalidity of Claims 1 and 3-7 of the '456 Patent Under 35 U.S.C. § 112, First Paragraph, for Lack of Enablement)

121. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 120, as if set forth in full.

122. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and Defendants concerning the validity of the claims of the '456 patent. Claims 1 and 3-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement.

123. Claim 1 is directed to any *in vitro* method for determining the presence of the G1849T mutation in the JAK2 gene in a human patient comprising three steps. The scope of

claim 1 is extremely broad and certainly much broader than the supporting disclosure. The claimed *in vitro* method is not limited in any way, *e.g.*, screening for a specific disease in a human patient, and encompasses any and all *in vitro* methods for determining the presence of the G1849T mutation in a human patient.

124. In addition, the *in vitro* method of claim 1 does not satisfy the utility requirement of 35 U.S.C. § 112, first paragraph. The *in vitro* method of claim 1 encompasses any and all *in vitro* methods for screening for the presence of the G1849T mutation in a human patient. Therefore, claim 1 encompasses, more than just the diagnostic uses referred to in the '456 patent to diagnose three specific myeloproliferative diseases, extending to any other unspecified uses.

125. Further, both claim 1 and claim 2 recite the step of "recording the presence of a T in the JAK2 gene at position 2343 of SEQ ID NO 2 in the sample," which appears as step (c) in both claims. This recording step is directed to any means for recording the presence of the recited JAK2 mutant in the claimed method, and thus is extremely broad.

126. Despite the breadth of the recording step of claims 1 and 2, the '456 patent, including its predecessor applications, do not provide any means for recording the presence of the JAK2 mutant. The "recording" step first appeared in a February 22, 2008 Amendment. (Ex. X) No support for that term appears either in the specification of the '359 application, in the Amendments submitted during accelerated examination, or in the updated AES document.

127. The '456 patent does not provide adequate direction or working examples to enable the full scope of claims 1 or 2. For instance, Examples 1 and 2 of the '456 patent, the latter of which was not added until the '586 PCT application, are directed to identifying the JAK2 mutation in PV patients and as a first intention diagnosis of erythrocytosis, respectively. Neither

of these generally stated examples provides sufficient guidance to enable one of ordinary skill actually to perform the methods as claimed.

128. In view of the breadth of claim 1 and the failure of the '456 patent to provide a specific utility or sufficient guidance to practice the claimed method, undue experimentation will be required to perform the full scope of the invention of claim 1.

129. In view of the breadth of the recording step of claims 1 and 2, undue experimentation will be required to perform the full scope of the invention of claims 1 and 2.

130. Accordingly, claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph.

131. Claims 3-7, which depend from claim 1, also are invalid under 35 U.S.C. § 112, first paragraph. These dependent claims merely limit the means for carrying out the analyzing step of claim 1. However, claims 3-7 do nothing to limit the scope of the *in vitro* method of claim 1 or the recording step of claim 1 and, therefore, would encompass any and all *in vitro* methods for determining or recording the presence of the JAK2 mutation in a human patient. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement.

COUNT VI

(Declaratory Judgment of Invalidity of Claims 1-7 of the '456 Patent Under 35 U.S.C. § 112, Second Paragraph, as Indefinite)

132. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 131, as if set forth in full.

133. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning the validity of the claims of the '456 patent. Claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as

indefinite because claims 1-7 of the '456 patent fail to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention," as required by 35 U.S.C. § 112, second paragraph.

134. 35 U.S.C. § 112, second paragraph, provides:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

135. The '456 patent does not provide any description or guidance as to the scope of the term "recording," which appears as step (c) in both claims 1 and 2 and would be necessary to apprise one skilled in the art of the scope of the invention. None of the applications provide any description or guidance, as well.

136. Claims 3-7 of the '456 patent depend either directly or indirectly from claim 1 and therefore contain each and every limitation of claim 1, including the recording step. Thus, claims 3-7 also are indefinite.

137. The "recording" step first appeared in a February 22, 2008 Amendment. (Ex. X) No support for that term appears either in the specification of the '359 application, in the Amendments submitted during accelerated examination, or in the updated AES document.

138. The '456 patent, and its predecessor applications, do not provide any means for recording the presence of the JAK2 mutant.

139. Claim 1 is also indefinite under 35 U.S.C. §112, second paragraph, because it refers to two different nucleotide numbers to designate the mutation to be detected in the method. The preamble of claim 1 of the '456 patent refers to nucleotide position "1849" in the JAK2 gene. However, steps (b) and (c) of issued claim 1 refer to nucleotide position "2343" of SEQ ID NO: 2.

140. The '456 patent provides no guidance to the relationship between the nucleotide position "1849" in JAK2 and nucleotide position "2343" in SEQ ID NO: 2 and only adds to the confusion. For example, SEQ ID NO: 2 in the predecessor applications and in the '456 patent is described (incorrectly) as "G1849T mutation in JAK2 gene." SEQ ID NO: 2 represent the genomic DNA (and includes the non-coding region). Thus, the sequence position corresponding to "1849" (when referring to the JAK2 coding region) is actually "2343" in SEQ ID NO: 2. There are numerous ATG sites in SEQ ID NO: 2, and it is unclear where translation begins.

141. The reference to two different nucleotide numbers in claim 1, in view of the lack of guidance provided in the predecessor applications and in the '456 patent, lacks the clarity necessary to allow a person of ordinary skill to precisely understand what infringes the claim.

142. Bio-Reference is entitled to a declaratory judgment that claims 1-7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as indefinite.

COUNT VII

(Declaration of Invalidity of Claims 1 and 2 of the '456 Patent Pursuant to 35 U.S.C. § 101 for Not Containing Patent-Eligible Subject Matter)

143. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 142, as if set forth in full.

144. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning the validity of the claims of the '456 patent. Claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101 for containing patent-ineligible subject matter.

145. Claim 1 of the '456 patent is directed to any *in vitro* method for determining the presence of the G1849T mutation in the JAK2 gene in a human patient comprising three steps.

(Ex. A, col. 45, lines 26-34) The three steps include an "obtaining and analyzing" step, a "detecting" step, and a "recording" step. *Id.* at lines 29-34.

146. Claim 2 of the '456 patent is directed to any *in vitro* method for diagnosing a human patient for an MPD selected from a group of three (3) disorders, wherein the presence of the T mutation at position 2343 of SEQ ID NO: 2 indicates the patient has, or is likely to have, the claimed disorders. *Id.* at lines 35-50. Claim 2 includes the same three steps as claim 1, an "obtaining and analyzing" step, a "detecting" step, and a "recording" step. *Id.* at lines 40-45.

147. Claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*) *cert. granted*, 129 S. Ct. 2735.

148. Claims 1 and 2 are not tied to a particular machine or apparatus. *Id.* at 954.

149. Claims 1 and 2 of the '456 patent do not transform a particular article into a different state or thing. *Id.*

150. The essence of the method for testing for the presence of the mutation or for diagnosing a patient for a MPD is nothing more than a mental process, which involves no transformation of any article into a different state or thing.

151. Bio-Reference is entitled to a declaratory judgment that claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101.

COUNT VIII

(Declaration That Defendants, Through Their Exclusive Licensees, The Ipsogens, Have Misused the '456 Patent)

152. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 151, as if set forth in full.

153. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning the impermissibility of their exclusive

licensees' and agents', the Ipsogens, market practices of the '456 patent. The Defendants committed patent misuse through the Ipsogens' attempts to license the '456 patent and the Ipsogens' misconduct requiring diagnostic laboratories to purchase JAK2 test kits for commercial purposes, putting those laboratories at risk of violating FDA regulations, in order to practice the claims of the '456 patent.

154. The Ipsogens' misconduct impermissibly broadened the scope of the '456 patent resulting in anticompetitive effects.

155. Upon information and belief, the Ipsogens broadened impermissibly the scope of '456 patent by tying their proposed license to the '456 patent to the purchase of the JAK2 kits. As shown in paragraphs 41 to 45, the '456 patent only covers tests that detect and record the presence of the JAK2 mutation. The '456 patent does not cover tests that detect and record the absence of the JAK2 mutation.

156. The Ipsogens' JAK2 kits constitute a separable, staple good because the JAK2 kits have substantial non-infringing uses. Every use of the Ipsogens' JAK2 kit that has a negative result for the JAK2 mutation falls outside the scope of the claims of the '456 patent.

157. By requiring licensees (through either express or implied licenses) to purchase the JAK2 kits to practice the claims of the '456 patent, even when the test does not find the JAK2 gene, Defendants, through their agents the Ipsogens, have broadened their patent grant through an impermissible tying arrangement.

158. Defendants and the Ipsogens together possess market power in the relevant market for diagnosis of MPD, particularly PV. The only substitute to the claimed methods of the '456 patents for diagnosis of MPD, particularly PV, is a higher cost and more burdensome bone

marrow culture test. By asserting rights under the '456 patent, the Ipsogens were able to drive this substitute largely out of the market.

159. As a result, the Defendants committed *per se* misuse of the '456 patent.

160. Even if the Defendants had not committed a *per se* patent misuse, the impermissible tying efforts and licensing efforts of its exclusive licensees and agents constitute patent misuse under a rule of reason and should be charged to the Defendants.

161. The Ipsogens license the '456 patent to a large number of clinical diagnostic laboratories.

162. Upon information and belief, the Ipsogens' standard licensing terms impose a royalty fee for each JAK2 test run regardless of whether the test detects and records the JAK2 mutation. This licensing practice impermissibly broadens the scope of the '456 patent.

163. Defendants and the Ipsogens together possess market power in the relevant market for clinical diagnosis of MPD, particularly PV.

164. Defendants' and the Ipsogens' licensing practices have anticompetitive effects in the market. In the case of its offer to Bio-Reference, the Ipsogens proposed a $35 royalty for each JAK2 test run by Bio-Reference. This $35 fee raises the marginal cost of materials for a JAK2 diagnostic test by three- to four-fold. This cost increase harms diagnostic laboratories, health insurers and patients, as this extracted cost is passed through the payment system.

165. Upon information and belief, the Defendants sanctioned the Ipsogens' misconduct. In any event, the Ipsogens are the agents of the Defendants.

166. Bio-Reference is entitled to a declaratory judgment that the Defendants, through their licensees and agents, the Ipsogens, misused the '456 patent and that the patent is therefore unenforceable.

COUNT IX

(Declaration of Non-Infringement of the '456 Patent)

167. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 166, as if set forth in full.

168. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning whether and to what extent Bio-Reference infringes any claim of the '456 patent. Bio-Reference's JAK2 mutation test does not infringe any valid claim of the '456 patent.

169. Even if deemed valid and enforceable, claims 4-7 of the '456 patent are not infringed, either literally or under the doctrine of equivalents, at least because Bio-Reference does not use hybridization with probes in their testing methods, as required by those claims.

170. Even if the claims of the '456 patent are determined to be enforceable and not to be invalid, Bio-Reference is entitled to a declaratory judgment that its V617F JAK2 test does not infringe, directly or indirectly, either literally or equivalently, claims 4-7 of the '456 patent.

171. Even if the claims of the '456 patent are determined to be enforceable and not to be invalid, Bio-Reference is further entitled to a declaratory judgment that its V617F JAK2 test does not infringe, directly or indirectly, either literally or equivalently, any claim of the '456 patent when it does not detect the presence of the V617F mutation in the JAK2 gene of a test sample.

172. Bio-Reference is entitled to a declaratory judgment that it does not infringe claims 4-7 of the '456 patent and that it does not infringe any claim of the '456 patent when Bio-Reference's test for the JAK2 mutation do not detect the presence of a T at the 2343 position of the JAK2 gene.

COUNT X

(Declaration of Relevant Royalty Base if Bio-Reference is Adjudged to Infringe a Valid, Enforceable Claim of the '456 Patent)

173. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 172, as if set forth in full.

174. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants concerning the proper scope of Bio-Reference's testing and/or testing revenues on which the Defendants can predicate a claim for damages in the event the Defendants prevail in an action for patent infringement of the '456 patent and the patent is not found invalid or unenforceable.

175. The Ipsogens, as licensees and agents of the Defendants, demanded that Bio-Reference pay an exorbitant royalty for, or purchase an Ipsogen kit in place of, all of Bio-Reference's JAK2 testing.

176. Even if relevant claims of the '456 patent were considered valid and enforceable, all of the claims of the '456 patent only cover tests that detect and record the presence of the JAK2 mutation. The claims of the '456 patent do not cover any tests that detect and record the absence of the JAK2 mutation.

177. Bio-Reference is entitled to a declaratory judgment that the Defendants only can base a claim for damages on testing that results in the detection and recording the presence, but not the absence, of the JAK2 mutation.

COUNT XI

(Declaration That The Ipsogens' Existing Licensing Agreements and/or Past Sale of JAK2 Kits Cannot be Used to Establish Damages)

178. Bio-Reference incorporates by reference the allegations contained in Paragraphs 1 to 177, as if set forth in full.

179. An actual controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Bio-Reference and the Defendants about whether the Defendants can rely on the Ipsogens' current and past commercial practice with licensees and JAK2 kit purchasers to establish damages owed by Bio-Reference to the Defendants.

180. The Ipsogens, as licensees and agents of the Defendants, demanded that Bio-Reference license the '456 patent and/or purchase the JAK2 kits in performing all JAK2 testing. The Ipsogens asserted that these conditions are consistent with its arrangement with other licensees and/or customers.

181. Bio-Reference contends that the Ipsogens' existing licenses and JAK2 sales were obtained by misuse of the '456 patent and by marketing the JAK2 kits in violation of FDA regulations. Because the Ipsogens' existing licensee and customer bases were obtained by unlawful conduct, Defendants should be barred from relying on evidence of the same to prove up any damage claim against Bio-Reference.

182. The Ipsogens' demands that Bio-Reference use the kits for commercial use despite the fact that the FDA approved those kits only for RUO constitutes a misuse of the '456 patent. Accordingly, the Ipsogens misused the '456 patent as to Bio-Reference and as to other licensees and customers.

183. The Ipsogens marketed the test kits to Bio-Reference and others in violation of FDA regulations.

184. Bio-Reference is entitled to a declaratory judgment that Defendants are barred from relying on any evidence of the Ipsogens' existing or past license agreements or JAK2 kits sales, to establish a remedy against Bio-Reference because Defendants, through their exclusive

licensees and agents, the Ipsogens, have licensed the '456 patent and marketed the JAK2 kits in an unlawful manner.

COUNT XII

(False and Misleading Advertising Under the Lanham Act, 15 U.S.C. § 1125(a))

185. Bio-Reference incorporates by reference the allegations contained in paragraphs 1 through 184 as if fully set forth herein.

186. On information and belief, Defendants, through their exclusive licensees and agents, the Ipsogens, sold the JAK2 test kits to clinical diagnostic laboratories.

187. The Defendants, through their exclusive licensees and agents, the Ipsogens, required Bio-Reference to purchase the JAK2 test kits even though the Ipsogens knew that Bio-Reference would use the kits for non-research purposes, including clinical diagnostic testing.

188. In offering to sell these kits to Bio-Reference, the Defendants, through their exclusive licensees and agents, the Ipsogens, falsely and misleadingly represented that the kits are FDA approved for clinical diagnostic testing.

189. The Ipsogens' JAK2 test kits are not approved for clinical diagnostic testing. The JAK2 test kits are approved solely for RUO.

190. Despite the RUO limitation, upon information and belief, Defendants, through their exclusive licensees and agents, the Ipsogens, required clinical diagnostic laboratories that conduct JAK2 testing to purchase the Ipsogens' JAK2 test kits. Upon information and belief, clinical diagnostic laboratories have purchased the test kits from the Ipsogens for use in clinical diagnostic testing.

191. Defendants, through their exclusive licensees and agents, the Ipsogens, supplied Bio-Reference's competitors with JAK2 test kits sold through false and misleading sales tactics,

and false and misleading representations of fact, including implicit misrepresentations that the test kits were FDA approved for clinical diagnostic testing.

192. Defendants', through their exclusive licensees and agents, the Ipsogens, false and misleading representations in their commercial advertising misrepresent the nature, characteristic, and quality of the JAK2 test kits, as the kits are not FDA approved for clinical diagnostic testing.

193. Defendants', through their exclusive licensees and agents, the Ipsogens, use of false and misleading representations regarding the JAK2 test kits in commerce constitutes unfair competition in violation of 15 U.S.C. § 1125(a). Bio-Reference has suffered and will continue to suffer irreparable injury and damages as a result of Defendants' acts.

194. As result, Bio-Reference is entitled to:

a. Preliminary and permanent injunctive relief enjoining both Defendants and the Ipsogens from representing, promoting, marketing, selling, or advertising the JAK2 test kits as FDA approved for clinical diagnostic testing, pursuant to 15 U.S.C. § 1116 and other applicable laws.

b. An award granting Bio-Reference monetary relief including, but not limited to, all damages caused by Defendants' and the Ipsogens' false and/or misleading advertising, Defendants' and the Ipsogens' profits, treble damages, and the costs of this action, including reasonable attorneys' fees and prejudgment interest, pursuant to 15 U.S.C. § 1117 and other applicable laws.

COUNT XIII

(Declaration That All Claims of the '456 Patent Are Unenforceable Due to Inequitable Conduct)

195. Bio-Reference incorporates by reference the allegations contained in paragraphs 1 through 194 as if fully set forth herein.

196. As prosecution counsel, Foley filed an Issue Fee Transmittal Form to the USPTO. That form contained false statements, specifically the false statement that identified "IPSOGEN, Marseilles (FR)" as the assignee of the '456 patent.

197. As signatories to the license agreement, the Defendants knew that "IPSOGEN, Marseilles (FR)" was a mere licensee and not an assignee at the time Foley filed the Issue Fee Transmittal Form with the USPTO.

198. All persons substantially involved with the prosecution of a patent application before the USPTO, including their attorneys, in this case, Foley, have a duty of candor towards the USPTO. *See, e.g.*, 37 C.F.R. § 1.56(a). Yet, at no time has Foley, the Defendants, or the Ipsogens notified the USPTO of the material false statement or attempted to correct the material false statement.

199. The Defendants intentionally deceived the USPTO by allowing the '456 patent to issue with "IPSOGEN, Marseilles (FR)" listed as the assignee, even though Defendants knew that statement to be false.

200. Defendants and Foley continue to intentionally deceive the USPTO because neither has taken any steps to correct the face of the '456 patent.

201. As prosecution counsel, Foley knew, or should have known, the identity of the owner or owners of the '456 patent. Foley knows, or should know, that listing the correct owner on the face of the patent is material to the public notice function of the patent.

202. Foley, Defendants, and the Ipsogens defeated the public notice function by allowing the '456 patent to issue to an incorrect owner.

203. Bio-Reference is entitled to a declaratory judgment that the '456 patent is unenforceable because of the fraud committed on the USPTO. That fraud constitutes inequitable conduct and renders the '456 patent and all of its claims unenforceable.

COUNT XIV

(Finding That This Case is Exceptional Pursuant to 35 U.S.C. § 285 Because of Defendants' Fraudulent Conduct Towards Bio-Reference)

204. Bio-Reference incorporates by reference the allegations contained in paragraphs 1 through 203 as if fully set forth herein.

205. Defendants knew or should have known that the Ipsogens fraudulently represented that they had "intellectual property rights" that were "enforceable" against Bio-Reference.

206. On May 15, 2008, the Ipsogens stated to Bio-Reference: "Should **our** US patent grant, we will expect that Bio Reference will respect **our** intellectual property rights and immediately stop all JAK2 in-house testing by means other than Ipsogen Kits." Ipsogen had no basis in fact or law to state to Bio-Reference, "[s]hould **our** US patent grant," when it knew that it was not the assignee of the putative patent.

207. Defendants knew or should have known that the Ipsogens misrepresented their ownership of the '456 patent and threatened to enforce the '456 patent in an infringement action against Bio-Reference in an effort to extract exorbitant license terms.

208. The Ipsogens made clear to Bio-Reference that they would enforce their "intellectual property rights" in the '456 patent if Bio-Reference refused to license the patent or purchase the test kits from the Ipsogens.

209. Neither of the Ipsogens disclosed their lack of ownership rights when seeking to license the patent to Bio-Reference, or when threatening litigation to enforce the '456 patent, a threat that neither Ipsogen party could make in good faith.

210. The Ipsogens' threats, coupled with the fraud committed on the USPTO, led Bio-Reference to file the related declaratory judgment action in the District of New Jersey and the instant action in the District of Columbia.

211. Defendants' fraudulent misrepresentations, through its licensees and agents, the Ipsogens, to Bio-Reference, and its fraud committed on the USPTO, caused Bio-Reference to incur substantial unnecessary legal fees.

212. Bio-Reference is entitled to recover its attorneys' fees and other costs because Defendants' misconduct towards Bio-Reference and its misconduct in dealing with the USPTO make this case exceptional pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Bio-Reference asks this Court to enter judgment in its favor against defendants as follows:

A. A judgment declaring that the claims of '456 patent are limited to detecting and recording the presence, but not the absence, of the T in the JAK2 gene at position 2343;

B. A judgment declaring that the claims of the '456 patent are entitled to a priority date no earlier than May 24, 2006;

C. A judgment declaring that claims 1 through 3 of the '456 patent are invalid under 35 U.S.C. §§ 102(b) and/or 102(a);

D. A judgment declaring that claims 1 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of written description;

E. A judgment declaring that claim 1 and claims 3 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, first paragraph, for lack of enablement;

F. A judgment declaring that claims 1 through 7 of the '456 patent are invalid under 35 U.S.C. § 112, second paragraph, as indefinite;

G. A judgment declaring that claims 1 and 2 of the '456 patent are invalid under 35 U.S.C. § 101;

H. A judgment declaring that Defendants misused the '456 patent, and the '456 patent is therefore unenforceable;

I. A judgment declaring that Bio-Reference does not infringe any claim of the '456 patent when its JAK2 testing does not detect the JAK2 mutation and a declaratory judgment that Bio-Reference does not infringe claims 4 through 7 of the '456 patent;

J. A judgment declaring that, if Bio-Reference is adjudged to infringe any claim of the '456 patent, Bio-Reference is only liable as to JAK2 testing in which particular tests actually detected and recorded the presence of the JAK2 mutation;

K. A judgment declaring that Defendants are barred from relying on evidence of the Ipsogens' existing licensing agreement and/or past sale of JAK2 kits to establish a claim for damages against Bio-Reference;

L. A judgment against Defendants for the Ipsogens' violation of the Lanham Act, 15 U.S.C. 1125(a), (i) entering a permanent injunction enjoining Defendants or the Ipsogens from representing, promoting, marketing, selling, or advertising the JAK2 test kits as FDA approved for clinical diagnostic testing, pursuant to 15 U.S.C. § 1116 and other applicable laws; and (ii) granting Bio-Reference monetary relief including, but not limited to, all damages caused by the Defendants and/or the Ipsogens, Defendants' and/or the Ipsogens' profits, treble damages, and the

costs of this action, including reasonable attorneys' fees and prejudgment interest, pursuant to 15 U.S.C. § 1117 and other applicable laws;

M. A judgment declaring that the '456 patent is unenforceable because of the fraud committed on the USPTO;

N. A judgment that this is an exceptional case and that Bio-Reference is entitled to recover its attorneys' fees and other costs pursuant to 35 U.S.C. § 285; and

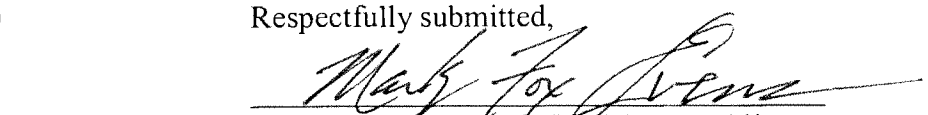
O. Granting Bio-Reference such other relief as the Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Bio-Reference demands a trial by jury of all matters to which they are entitled to a trial by jury.

Dated: February 19, 2010

Respectfully submitted,



Mark Fox Evens (D.C. Bar No. 343723)
Byron L. Pickard (D.C. Bar No. 499545)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, D.C. 20005-3934
(202) 371-2600

Of Counsel:
Jorge A. Goldstein
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, D.C. 20005-3934
(202) 371-2600

Attorneys for Plaintiff
Bio-Reference Laboratories, Inc.